

Chapter XI

Acute Care

XI. Acute Care

Mississippi had 96 non-federal medical/surgical hospitals in April 2004, with a total of 11,501 licensed general acute care beds. In addition, numerous facilities provide specific health care services on an outpatient basis. Some of these facilities are freestanding; others are closely affiliated with hospitals. Such facilities offer an increasingly wider range of services, many of which were once available only in inpatient acute care settings. Examples include diagnostic imaging, therapeutic radiation, and ambulatory surgery.

General Medical/Surgical Hospitals

The 96 facilities classified as general medical/surgical hospitals reported 10,478 beds set up and staffed during 2003, or 91.11 percent of the total licensed bed capacity. Based on beds set up and staffed, the hospitals experienced an overall occupancy rate of 51.63 percent and an average length of stay of 4.99 days. If the occupancy rate were calculated using total licensed bed capacity, the overall occupancy rate drops to 47.00 percent. Using these statistics and 2005 estimated population totals, Mississippi had a licensed bed capacity to population ratio of 3.8 per 1,000 and an occupied bed to population ratio of 1.85 per 1,000.

These statistics indicate an average daily census in Mississippi hospitals of 5,410, leaving approximately 6,091 unused licensed beds on any given day. Fifty-six of the state's hospitals reported occupancy rates of less than 40 percent during FY 2003. Officials expect the low occupancy rates to continue because of cost-containment pressures and the increased use of outpatient services. This situation places extreme financial burdens on small rural hospitals, and many of them must alter their scope of services if they expect to survive as health care facilities.

The changing nature of the health care industry causes hospitals to look for new services or convert existing facility space to more profitable uses. Hospitals show increasing interest in providing more outpatient services and expanding into such areas as home health and long-term care. Conversion of hospital beds to long-term care beds (nursing home, personal care, or assisted living) may be a viable alternative to closure of small rural hospitals. Many of these hospitals could meet long-term care licensure and certification requirements without great capital outlay. The conversion of existing hospital beds to long-term care would serve two purposes: a) alleviating some of the state's shortage of nursing home beds at less cost than new construction; and b) helping small financially troubled rural hospitals remain economically viable.

Construction, Renovation, Expansion, Capital Improvements, Replacement of Health Care Facilities, and Addition of Hospital Beds

Most of Mississippi's general acute care hospitals were built many years ago under the Hill-Burton Program and now need major renovation or replacement. Continual changes in building codes, the increasing competition for patient markets, and other factors have increased the pressure for facility construction, renovation, expansion, or replacement.

The migration of specific health care services from inpatient-oriented environments to outpatient/ambulatory facilities has increased the number of projects for new or expanded facilities to house these services. Both freestanding and hospital-affiliated health care facilities now provide therapeutic radiation, diagnostic imaging, ambulatory surgery, and other services in settings other than hospitals.

Mississippi requires Certificate of Need (CON) review for all projects that increase the bed complement of a health care facility or exceed a capital expenditure threshold of \$2 million. The law requires Certificate of Need review regardless of capital expenditure for the construction, development, or other establishment of a new health care facility, including a replacement facility; the relocation of a health care facility or any portion of the facility which does not involve a capital expenditure and is more than 5,280 feet from the main entrance of the facility; and a change of ownership of an existing health care facility, unless the MSDH receives proper notification at least 30 days in advance. Finally, a CON is required for major medical equipment purchase if the capital expenditure exceeds \$1.5 million and is not a replacement of existing medical equipment.

Long-Term Acute Care Hospitals

A long-term acute care (LTAC) hospital is a free-standing, Medicare-certified hospital with an average length of inpatient stay greater than 25 days that is primarily engaged in providing chronic or long-term medical care to patients who do not require more than three hours of rehabilitation or comprehensive rehabilitation per day. Mississippi's first such hospital opened in 1993. As of March 2004, six long-term acute care hospitals are in operation. Listed below are the LTAC facility name by bed capacity, percent occupancy rate (OR), number of discharges, and average length of stay (ALOS).

Long-Term Acute Care Hospitals 2003

Facility	Beds	OR%	Discharges	ALOS
Miss. Hospital for Restorative Care	25	76.83	246	34.21
Regency Hospital of Hattiesburg	33	CON	CON	CON
Regency Hospital of Meridian	40*	34.88	104	27.05
Select Specialty Hospital of Biloxi	42	50.02	326	24.33
Select Specialty Hospital of Gulfport	38	54.88	300	26.01
Select Specialty of Jackson	40	34.82	179	13.93
Specialty Hospital of Meridian	49	92.52	638	25.54
Tri-Lakes Medical Center	35	CON	CON	CON
Vicksburg Specialty Medical Center	35	CON	CON	CON
TOTAL**	337	59.39	1,793	25.34

* Calculated for 30 beds and 257 days in reporting period.

** Calculated for 224 beds.

Rural Acute Care Hospitals

Currently, 77 of the 96 non-federal acute care hospitals in the state reside in rural areas (located outside of Metropolitan Statistical Areas). These 77 hospitals represented 57.9 percent of the total number of licensed acute care beds in 2003. Of these 77 rural hospitals, 21 (27.3 percent) have 100 or more beds; 18 (23.4 percent) have 50-99 beds; and 38 (49.34 percent) have fewer than 50 beds.

The pressures of a rapidly changing health care environment affect the financial viability of many rural hospitals. These hospitals face limited revenues, inadequate population bases, and regulatory constraints. A limited scope of services and fewer technological resources make it difficult to compete for patients and physicians, causing low patient volume which results in higher costs per case. Federal government studies show that the risk of hospital closure is highest among hospitals that operate fewer than 100 beds, have occupancy rates of 40 percent or less, or have a large percentage of Medicaid days (11 percent or more). The studies did not find Medicare reimbursement, in itself, a significant risk factor.

The studies also found that hospitals with fewer than 50 beds and occupancy rates of less than 20 percent face a higher risk of closure. Other significant risk determinants include the area's unemployment rate, low per capita income, and competition from other hospitals. In 2003, 44 of Mississippi's rural hospitals with less than 100 beds (78.6 percent) reported occupancy rates of 40 percent or below. Thirty-two of the 38 hospitals with fewer than 50 beds (84.2 percent) reported occupancy rates of less than 40 percent, and six of these hospitals (15.8 percent) had rates under 20 percent.

A number of alternatives have emerged as administrators and hospital boards attempt to cope with the increasing distress experienced by the nation's rural hospitals, particularly the smaller ones. One possibility is to diversify a hospital's activities by adding new services to offset dwindling inpatient demand. Another alternative is forming alliances of rural hospitals to achieve better economies of scale in areas such as purchasing or acquisition of new resources, while maintaining individual autonomy. A number of rural hospitals have entered into more formal multi-hospital arrangements where the hospital is owned, leased, or managed by another larger hospital or parent corporation. This arrangement usually diminishes the autonomy of the individual hospital. The number of multi-hospital arrangements in Mississippi has grown in the past several years. Six such arrangements existed in the spring of 2004. The six networks involve 45 of Mississippi's hospitals, and all but seven are rural.

The federal government took several actions to help rural hospitals, such as increasing reimbursement through changes in the Medicare prospective payment system. Other actions include programs to use excess hospital beds, modify services, recruit physicians, and encourage participation in consortia with other local providers to expand, improve, or initiate new services. A number of these activities specifically target rural hospitals: the swing-bed program, the small Medicare-dependent hospitals provision, Rural Health Outreach grants, and Rural Health Network grants. These grants encourage hospitals to form consortia with other providers to deliver new services to unserved rural populations. Congress also changed the Rural Health Clinic Act to encourage the establishment of freestanding or hospital-based clinics using mid-level practitioners, with services reimbursed on a cost basis for hospitals under 50 beds. Congress also increased funding for the National Health Service Corps, which could increase inpatient physician referrals to hospitals located in Health Professional Shortage Areas.

After several years of funding demonstration projects, a new classification of small rural hospital, called a critical access hospital, was established in 1997 by the federal government. The critical access hospital, or CAH, is eligible to receive cost-based reimbursement for services provided to Medicare patients. In return, the facility is limited in the number of inpatient beds that can be operated and the length of time that a patient can stay in that hospital. A more detailed description of the CAH program is found in the following section.

Responsibility for the difficulties of small rural hospitals lies with no single factor. However, the inability to retain primary care physicians or find replacements for retiring physicians can devastate hospitals already experiencing a low inpatient census. Possible ways to help recruit

and retain physicians include: (a) new methods of medical student selection and education that encourage students to consider practice in rural areas; (b) incentives to help physicians start a rural medical practice; (c) incentives to practice in an economically depressed area; and (4) providing coverage for physicians during leave.

In rural areas where demographics will not support the necessary physicians, officials should consider restructuring the hospital to provide continued access to primary care and referral. There are growing examples throughout the country of local community initiatives and state legislative action to encourage the elimination of acute care services in small rural hospitals, converting the facilities to provide other types of health care services.

Individual small rural hospitals will continue to experience multiple pressures in the foreseeable future, which will affect their ability to provide acute inpatient care. Mississippi needs increased collaborative efforts by health care providers, local communities, the state, and the federal government to assure that rural citizens have reasonable access to a full range of health care services. This goal may be best achieved through systems of health care in which the small rural hospital is one component, though not necessarily the inpatient component.

History of Limited Service Hospitals and the Evolution of Critical Access Hospitals

A limited service hospital provides an alternative for rural communities that can no longer support a full service hospital. Through relaxed staffing, service, and hours of operation requirements, it provides regulatory relief to facilities that obtain certification as a limited service hospital. Critical to the financial feasibility of this model, and what is most attractive to rural hospital stakeholders, is cost-based reimbursement from Medicare for inpatient and outpatient services.

Congress authorized a limited service hospital model for all states with the Medicare Rural Hospital Flexibility Program, established through the Balanced Budget Act of 1997 (P.L.105-33 Section 4201) and the Balanced Budget Refinement Act of 1999. This program allows states that develop a comprehensive rural health care plan approved by the Centers for Medicare and Medicaid Services (CMS) to designate applicant rural hospitals that meet certain criteria as Critical Access Hospitals (CAH). Minimum requirements for CAHs are as follows:

Location and Status:

- Hospital must be rural (non-metropolitan statistical area).
- Hospital must be deemed by the state as a necessary provider of services to the community.
- Hospital must have a current participation agreement with Medicare.

Service Limits:

- Patients may not stay for longer than an average of 96 hours (except under certain conditions). Patients requiring a longer stay must be transferred to a full-service hospital.
- Hospital may have no more than 25 acute care beds and may offer swing bed services up to the 25-bed limitation.

Medical Staff:

- At least one physician (doctor of medicine or osteopathy) must be on staff. Mid-level practitioners may be the primary provider of care, but only under the supervision of the physician.
- Nursing staff must be on duty in the facility when the CAH has one or more patients.

- Staff must be sufficient to provide the services essential to the operation of the CAH.

Services Required:

- Inpatient and emergency care, laboratory and x-ray services are required. Some ancillary (lab, radiology) may be provided part-time off-site.
- Emergency services are required 24 hours a day, seven days a week. Staff in the emergency room must have emergency services training/experience.
- A system must be in place with the local emergency medical system so that emergency medical personnel are aware of who is on call and how to contact them.
- A doctor of medicine or osteopathy must be available by phone or radio 24 hours a day, seven days a week.

Networks:

- Each CAH must be a member of a network including a larger facility, with agreements maintained for patient referral and transfer, emergency and non-emergency transportation, and development and use of a communication system between the network members.
- Additional arrangements must be in place.

The 1998 session of the Mississippi Legislature authorized the MSDH to develop a state rural health care plan, to adopt rules and regulations for the designation of CAHs and rural health networks, and to provide for insurance reimbursement for services provided by CAHs if such services would be covered if provided in a full service hospital. The legislation states that “it is the policy of the State of Mississippi to provide improved access to hospitals and other services for rural residents of the State of Mississippi and to promote regionalization of rural health services in Mississippi.”

The *Mississippi Rural Health Care Plan*, developed by the Division of Health Planning and Resource Development, identifies 28 rural Mississippi hospitals as potential candidates for conversion to a CAH. These hospitals were identified as necessary providers of services to their community and were identified as at risk of closure due to falling into at least one of the following criteria: smaller hospital size, lower inpatient occupancy rates, lower Medicare days, higher Medicaid days, higher area wages, and more local competition. Sixteen CAHs are operational, with an additional hospital approved for reclassification and awaiting its CMS surveys.

Swing-Bed Programs and Extended Care Services

Rural hospitals once routinely provided both acute and long-term care, but the practice largely disappeared with the inception of Medicare and Medicaid in the mid-1960s. Regulatory requirements for Medicare and Medicaid reimbursement mandated that a hospital providing extended or long-term care do so in a physically distinct part of the institution exclusively designated for such care. The regulations also required certain specialized services and used the reimbursement mechanism to impose financial restraints. Therefore, many rural hospitals discontinued long-term care unless they also operated separate nursing homes.

In 1980 Congress amended the Social Security Act to allow rural hospitals of fewer than 50 beds to provide extended or long-term care in acute care beds and receive reimbursement from Medicare and Medicaid at long-term care rates. In 1988 Congress expanded the provisions to include hospitals of up to 100 beds. The program allows participating hospitals to use designated beds for both acute care and nursing facility patients. In effect, the beds "swing" between the two types of care, thus creating the term "swing-beds".

The swing-bed concept does not refer to beds designated as nursing home beds and does not necessarily involve moving beds or patients into separate areas of the hospital. Nursing home beds are generally occupied for periods ranging from a few months to years. Swing-beds, on the other hand, alternate between acute and long-term care. Patients occupy swing-beds for a few days to several weeks. For that reason, care provided through the swing-bed concept is often referred to as extended care.

Although Congress intended to reduce regulatory restraints that limited the use of swing-beds, hospitals must meet several requirements for certification as swing-beds under Medicare and Medicaid. Federal certification requirements focus on eligibility, skilled nursing facility services, and coverage requirements. Eligibility criteria include the following:

- A hospital must be located in a rural area (any geographic area not designated as "urban" by the most recent census);
- A hospital must operate fewer than 100 beds, excluding bassinets and intensive-care beds;
- A hospital must obtain a Certificate of Need if required by the state; and
- A hospital may not have in effect a 24-hour nursing waiver granted under the flexibility of personnel standards.

In addition to meeting acute care standards, swing-bed hospitals must also meet six standards for nursing facility services. These standards involve patients' rights, dental services, specialized rehabilitative services, social services, patient activities, and discharge planning. Swing-bed hospitals have the same Medicare coverage requirements and coinsurance provisions as nursing facilities, as follows:

- Nursing facility days in a swing-bed hospital are counted against the total number of nursing facility benefit days available to Medicare beneficiaries;
- A nursing facility swing-bed patient must have three consecutive calendar days of inpatient hospital care prior to transfer to nursing facility care; and
- Medicare beneficiaries must receive nursing facility care within 30 days of discharge from inpatient acute care.

Patients who are ready for discharge from the hospital often experience difficulty finding a nursing home where they can continue recuperation. This situation causes hospital costs to be higher than necessary when nursing home transfers are delayed due to a lack of available beds. Mississippi has very few Medicare-certified nursing home beds; therefore, many patients are unable to utilize the Medicare nursing facility benefit. Moreover, the state may have to pay for nursing facility care through the Medicaid program that could otherwise be funded through Medicare. The use of swing beds could help alleviate such problems without new construction and with mostly Medicare funds.

Additionally, the swing-bed concept could reduce some of the future need for dedicated nursing home beds, thus reducing the need for new construction. Many patients, particularly elderly patients, no longer need acute hospital care but are not well enough to go home. Swing-beds enable the hospital to provide nursing care, rehabilitation, and social services with a goal of returning patients to their homes. Many of these patients would become nursing home residents without the extended period of care received in a swing-bed.

Swing-beds provide a link between inpatient acute care and home or community-based services in a continuum of care for the elderly and others with long-term needs. If return to the community is not possible, the swing-bed hospital assists the patient and family with nursing home placement. The swing-bed concept may help alleviate the problem of low utilization in small rural hospitals and provide a new source of revenue with few additional expenses. Additionally, swing-beds allow hospitals to better utilize staff during periods of low occupancy in acute care beds.

Swing-Bed Utilization

The number of hospitals participating in the swing-bed program has increased from four in 1982 to 52 in 2004. These hospitals reported 5,121 admissions to swing beds during Fiscal Year 2003, with 65,619 patient days of care and an average length of stay of 12.81 days. The number of days of care provided in swing beds was equivalent to approximately 179 nursing home beds.

The swing-bed program offers a viable alternative to placement in a nursing home for short-term convalescence. Only about 14.65 percent of the patients who were cared for in a swing-bed during 2003 were discharged to a nursing home, and 32.15 percent were referred to home health. Many more of these patients may well have ended up in a nursing home if swing-bed services had not been available.

Therapeutic Radiation Services

Radiation therapy uses ionizing radiation to treat disease, primarily cancer. It may be used in combination with surgery and/or chemotherapy, depending on the characteristics of the tumor or neoplasm. Approximately 50 to 60 percent of new cancer patients undergo some type of radiation therapy, either alone or combined with other treatments.

There are two categories of radiation therapy: a) brachytherapy, which uses sealed radioactive sources to deliver radiations at short distances by interstitial, intracavitary, or surface applications; and b) external beam radiation therapy through the use of megavoltage x-ray therapy units, such as linear accelerators, or Cobalt-60 teletherapy units, such as Gamma Knife or heavy-ion accelerators.

"Gamma Knife or Gamma unit" means a specialized type of equipment used to perform stereotactic radiosurgery on small brain tumors and vascular malformations using multiple Cobalt-60 gamma radiation sources focused through a collimator helmet and arrayed in a semicircular arc so that they may be very precisely focused and the radiation dose may be very precisely distributed, permitting treatment in neurosurgical cases where the site is inaccessible or otherwise unsuitable for other invasive methods.

"Gamma knife procedure" means a single treatment of a patient using the unit. Usually only one procedure is performed per patient, but it is possible that the procedure could be repeated if deemed clinically necessary.

"Stereotactic radiosurgery" means a non-invasive therapeutic procedure in which narrow beams of radiant energy are directed at the treatment target in the head so as to produce tissue destruction, using computerized tomography (CT), radiography, magnetic resonance imaging (MRI), and angiography for localization. Central Mississippi Medical Center and UMC are the only hospitals within the state with a CON to provide Gamma Knife Stereotactic Radiosurgery. Central Mississippi Medical Services reported 150 (72 inpatient and 78 outpatient) procedures during 2003.

Eight hundred fifty-seven (857) patients received brachytherapy radiation implantation in fifteen of the state's hospitals.

Mississippi law requires Certificate of Need review for therapeutic radiation services regardless of the capital expenditure if the proposed provider has not offered these services on a regular basis within 12 months prior to the time the provider proposes to offer such services. The acquisition or otherwise control of therapeutic radiation equipment is reviewable if the equipment costs in excess of \$1.5 million. For health planning and CON purposes, a Cobalt-60 unit (other than Gamma Knife), when operated in conjunction with therapeutic radiation modalities in a comprehensive cancer treatment center, will be counted as one-half equivalent to a linear accelerator. When a Cobalt-60 unit is the single modality of radiation therapy offered at a cancer treatment center, the Cobalt-60 equipment shall not be counted in the inventory relative to need determination.

Table XI-1 presents the facilities offering megavoltage therapeutic radiation therapy.

Table XI-1
Facilities Reporting Megavoltage Therapeutic Radiation Services
by General Hospital Service Area
FY 2002 and FY 2003

Facility	Number and Type of Unit	Number of Treatments (Visits)	
		2002	2003
General Hospital Service Area 1		26,595	24,471
Baptist Memorial Hospital-Golden Triangle, Columbus	1 - Linear Accelerator (18MV)	8,297	8,200
Baptist Memorial Hospital-North Mississippi, Oxford	1 - Linear Accelerator (20MV)	786	219
Magnolia Radiation Oncology Center, Corinth	1 - Linear Accelerator (6-15MV)	3,788	3,713
North Mississippi Medical Center, Tupelo	2 - Linear Accelerators (6MV & 18MV)	13,724	12,339
General Hospital Service Area 2		20,008	20,034
Baptist Memorial Hospital-Desoto, Southhaven	2 - Linear Accelerator (18MV & 18MV)	6,006	6,446
Bethesda Regional Cancer Center of NW MS, Clarksdale (freestanding)	1 - Linear Accelerator (6MV)	3,613	3,221
Bethesda Regional Cancer Treatment Center, Greenville (freestanding)	2 - Linear Accelerators (10MV & 6MV)	3,435	4,410
North Central MS Cancer Center, Greenwood (freestanding)	1 - Linear Accelerator (6MV)	6,954	5,957
General Hospital Service Area 3		68,349	59,864
Cancer Center of Vicksburg (freestanding)	1 - Linear Accelerator (6MV)	5,078	5,833
Central Mississippi Medical Center, Jackson	2 - Linear Accelerators (6MV & 18 MV)	15,561	6,552
Mississippi Baptist Medical Center, Jackson	3 - Linear Accelerators (18MV, 18MV, & 6MV)	26,496	26,861
St. Dominic/Jackson Memorial Hospital, Jackson	2 - Linear Accelerators (18MV & 18MV)	10,955	10,379
University Medical Center, Jackson	2 - Linear Accelerators (10MV & 4MV)	10,259	10,239
General Hospital Service Area 4		10,936	10,533
Anderson Cancer Center, Meridian	3 - Linear Accelerators (23EX, CL-18 & C16/100)	10,936	10,533

Table XI-1 (continued)
Facilities Reporting Megavoltage Therapeutic Radiation Services
by General Hospital Service Area
FY 2002 and FY 2003

Facility	Number and Type of Unit	Number of Treatments (Visits)	
		2002	2003
General Hospital Service Area 5		7,429	7,289
Cancer Care and Diagnostic Center, Natchez (freestanding)	1 - Linear Accelerator (6MV)	3,682	4,286
Southwest Mississippi Regional Medical Center, McComb	1 - Linear Accelerator (18MV)	3,747	3,003
General Hospital Service Area 6		15,954	15,853
Forrest General Hospital, Hattiesburg	2 - Linear Accelerator (15MV & 6MV)	12,393	12,190
South Central MS Cancer Center, Laurel (freestanding)	1 - Linear Accelerator (6MV)	3,561	3,663
General Hospital Service Area 7		16,000	17,088
Biloxi Radiation Oncology Center, Biloxi	1 - Linear Accelerator (6MV)	4,324	3,170
Memorial Hospital at Gulfport, Gulfport	2 - Linear Accelerators (15MV & 6MV)	7,549	9,373
Singing River Hospital	2 - Linear Accelerators (18MV & 18 MV)	4,127	4,545
State Total		165,271	155,132

Sources: Applications for Renewal of Hospital License for Calendar Years 2003 and 2004 and Fiscal Years 2002 and 2003
Annual Hospital Reports

Diagnostic Imaging Services

Diagnostic imaging equipment and services, except for magnetic resonance imaging and invasive digital angiography, are reviewable under the state's Certificate of Need law only when the capital expenditure for the acquisition of the equipment and related costs exceeds \$1.5 million. The provision of invasive diagnostic imaging services, i.e., invasive digital angiography, and the provision of magnetic resonance imaging services require a Certificate of Need if the proposed provider has not offered the services on a regular basis within 12 months prior to the time the services would be offered, regardless of the capital expenditure.

Equipment in this category includes, but is not limited to: ultrasound, diagnostic nuclear medicine, digital radiography, angiography equipment, computed tomographic scanning equipment, magnetic resonance imaging equipment, and position emission tomography.

Computed Tomographic (CT) Scanning

Should the capital expenditure for the acquisition of fixed or mobile CT scanning services, equipment, and related costs exceed \$1.5 million, the CON proposal will be reviewed under the general review criteria outlined in the most recent *Certificate of Need Review Manual* adopted by the Mississippi State Department of Health and the following utilization standards:

A proposed unit must be able to generate a minimum of 2,000 HECTs (See Table XI-2 for HECT conversion table) by the second year of operation.

Providers desiring CT capability must be properly utilizing 20,000 general radiographic imaging procedures per year.

Table XI-2
Head Equivalent Conversion Table (HECT)

Type of Scan	Yearly Number of Patients	Conversion Factor	HECTs*
Head without Contrast	500	1.00	500
Head with Contrast	500	1.25	625
Head with and without Contrast	200	1.75	350
Body without Contrast	100	1.50	150
Body with Contrast	200	1.75	350
Body with and without Contrast	300	2.75	825

* Formula: Yearly Number of Patients X Conversion Factor = HECTs

Magnetic Resonance Imaging (MRI)

Magnetic resonance imaging (MRI) is a diagnostic imaging technique that employs magnetic and radio-frequency fields to produce images of the body non-invasively. Magnetic resonance imaging is similar to CT scanning in that it produces cross-sectional and sagittal images without potentially harmful ionizing radiation, producing an image not distorted by bone mass. The equipment and its operational specifications continue to be refined. Optimum utilization of a single MRI machine ranges between 2,000 and 2,500 procedures per year.

Thirty-five facilities (hospitals and free-standing) in Mississippi operated fixed MRI units in FY 2003; another 35 facilities offered the service on a mobile basis (one or two days each week); and four facilities operated both fixed and mobile units. These 74 facilities performed a total of

200,728 MRI procedures during 2003. Two additional facilities received Certificate of Need approval during the year to provide MRI services. Table XI-3 presents the location, type (fixed or mobile), and utilization of MRI equipment throughout the state in 2002 and 2003.

Digital Subtraction Angiography (DSA)

Digital Subtraction Angiography (DSA) is a diagnostic imaging procedure that combines a digital processing unit with equipment similar to that used for standard fluoroscopic procedures. A radiopaque dye is injected into the patient; a computer then compares the pre-injection and post-injection images and subtracts any interfering bone and tissue structures obscuring the arteries. The X-ray pictures are converted to a digital form, which can be electronically manipulated and stored. Through the electronic manipulation, the images can be enhanced and further refined to give detailed information about the patient's vascular anatomy without additional X-ray exposure.

In some cases, the use of DSA may eliminate the need for arterial catheterization, which many times carries a higher risk factor. Because the digital method is more sensitive to contrast materials, a lesser amount is generally needed in a given area, and intravenous injection of contrast may be sufficient. When required, intra-arterial injection can be done using less contrast per study.

Due to its relative safety and good patient acceptance, DSA may be performed on a repeat basis in cases where risk and cost of conventional angiography might otherwise preclude a series of follow-up studies. Such studies can provide valuable information regarding the natural history of a variety of vascular diseases and the long-term results of various therapeutic interventions. DSA also allows safer screening of the elderly, who have a high risk of cerebrovascular disease.

Most DSA studies can be performed in less than one hour and are appropriate as an outpatient procedure, whereas conventional angiography usually requires a hospital stay of one or two days. Twenty-seven hospitals in the state provide DSA and reported 36,841 procedures during 2003.

DSA equipment performs several types of procedures. These procedures include examination of the carotid arteries, intracranial arteries, renal arteries, aortic arch, and peripheral leg arteries. A variety of anatomical and functional studies of the heart and coronary arteries are also performed.

Table XI-3
Location and Number of MRI Procedures by General Hospital Service Area
FY 2002 and FY 2003

Facility	Location	Type Equipment	Number of MRI Procedures	
			2002	2003
General Hospital Service Area 1			35,787	43,369
Baptist Memorial Hospital	Booneville	M	561	566
Baptist Memorial Hospital - Golden Triangle	Columbus	F(2)	4,014	4,804
Baptist Memorial Hospital - North Mississippi	Oxford	F(2)	4,068	4,400
Baptist Memorial Hospital - Union County	New Albany	F	2,119	2,069
Clay County Medical Center	West Point	M	440	666
Gilmore Memorial Hospital	Amory	M	1,195	1,295
Grenada Lake Regional Medical Center	Grenada	M	1,258	1,828
Health South Radiology Clinic	Columbus	F	838	1,135
Iuka Hospital	Tishomingo	M	564	653
Magnolia Regional Health Center	Corinth	F (2)	3,933	4,238
Medical Imaging and Diagnostics, LLC	Tupelo	F	CON	2,633
North Mississippi Medical Center	Tupelo	F (4)	15,339	16,622
Oktibbeha County Hospital	Starkville	M	1,310	1,368
Preferred Imaging, LLC	Batesville	M	CON	680
Trace Regional Hospital	Chickasaw	M	145	136
Tri Lakes Medical Center	Batesville	M	3	0
Yalobusha General Hospital	Water Valley	M	CON	276
General Hospital Service Area 2			14,196	15,545
Baptist Memorial Hospital - DeSoto	Southaven	F(1) M (1)	3,727	3,932
Bolivar Medical Center	Cleveland	M	1,092	2,634
Delta Regional Medical Center	Greenville	F(2)	1,547	1,463
Carvel Diagnostic Imaging	Olive Branch	F	1,730	2,158
Greenwood Leflore Hospital	Greenwood	F	3,931	3,248
Humphreys County Memorial Hospital	Belzoni	M	0	0
Kings Daughters Hospital	Greenville	M	240	470
Northwest Mississippi Regional Medical Center	Clarksdale	M	1,142	1,110
South Sunflower County Hospital	Indianola	M	441	329
University Hospital and Clinic - Holmes County	Lexington	M	304	201
General Hospital Service Area 3			54,344	64,579
Baptist Madison Imaging Center	Madison	M	CON	CON
Central Mississippi Diagnostics	Jackson	F	1,938	2,130
Central Mississippi Medical Center	Jackson	F	4,377	4,544
Hardy Wilson	Hazlehurst	M	0	0
Kings Daughters Hospital	Brookhaven	M	714	975
Kosciusko Medical Clinic	Kosciusko	M	1,690	2,299
Madison Imaging	Madison	F	CON	1,136
Magee General Hospital	Magee	M	463	668
Mississippi Baptist Medical Center	Jackson	F(2)(M)	6,443	11,598
Mississippi Diagnostic Imaging Center	Flowood	F(2)	8,450	8,289
Mississippi Sports Medical and Orthopedic	Jackson	F	2,641	2,705
Open MRI of Jackson	Jackson	M	1,513	1,605
Rankin Medical Center	Brandon	M	1,835	1,705
Ridgeland Diagnostic Center	Ridgeland	M	CON	154
River Region Health System	Vicksburg	F	3,003	3,327
Scott Regional Hospital	Morton	M	216	162
SE Lackey Memorial Hospital	Forrest	M	61	130
Southern Diagnostic Imaging Center	Flowood	F	3,255	4,014
St. Dominic/Jackson Memorial Hospital	Jackson	F(2)(M)	9,490	9,435
University Medical Center	Jackson	F(3)	8,255	9,373
Vicksburg Diagnostic Imaging	Vicksburg	M	—	330

Table XI-3 (continued)
Location and Number of MRI Procedures by General Hospital Service Area
FY 2002 and FY 2003

Facility	Location	Type Equipment	Number of MRI Procedures	
			2002	2003
General Hospital Service Area 4			10,011	12,529
Neshoba General Hospital	Philadelphia	M	693	1,038
Newton Regional Hospital	Newton	M	CON	233
Regional Medical Support Center, Inc.	Meridian	F (3)	7,330	7,282
Rush Medical Group	Meridian	F	1,988	3,976
General Hospital Service Area 5			2,447	5,772
Natchez Community Hospital	Natchez	M	207	153
Open Air of MS-LOU, LLC	Natchez	F	0	3,103
Southwest Mississippi Regional Medical Center	McComb	F	2,240	2,516
General Hospital Service Area 6			26,171	27,103
Forrest General Hospital	Hattiesburg	F	6,937	6,200
Hattiesburg Clinic, P.A.	Hattiesburg	F	6,905	6,763
Open MRI, Inc.	Laurel	M	1,315	1,946
South Central Regional Medical Center	Laurel	F	3,860	3,797
Southern Bone and Joint Specialist, P.A.	Hattiesburg	F	3,540	3,807
Southern Medical Imaging	Hattiesburg	F	276	1,117
Wesley Medical Center	Hattiesburg	F	3,338	3,473
General Hospital Service Area 7			28,731	31,831
Biloxi Regional Medical Center	Biloxi	F	4,419	5,578
Coastal MRI	Gautier	M	1,725	1,628
Garden Park	Gulfport	F	1,775	1,116
George County Hospital	Lucedale	M	7	495
Gulf Coast Medical Center	Biloxi	F	1,618	1,635
Hancock Medical Center	Bay St. Louis	F	1,955	1,981
L.O. Crosby Memorial Hospital	Pearl River	M	984	988
Memorial Hospital at Gulfport	Orange Grove	F	CON	CON
Memorial Hospital at Gulfport	Gulfport	F(1) M(1)	5,706	5,458
Ocean Springs Hospital	Ocean Springs	F	2,304	2,804
Open MRI, Inc.	Gulfport	M	4,993	6,659
Singing River Hospital	Pascagoula	F	3,245	3,489
State Total			171,687	200,728

F - Fixed Unit

M - Mobile Unit

Sources: Applications for Renewal of Hospital License for Calendar Year 2003 and 2004, and Fiscal Years 2002 and 2003 Annual Hospital Reports

Positron Emission Tomography (PET)

Positron emission tomography (PET) is a minimally invasive imaging procedure in which positron-emitting radionuclides, produced either by a cyclotron or by a radio-pharmaceutical producing generator, and a gamma camera are used to create pictures of organ function rather than structure. PET scans provide physicians a crucial assessment of the ability of specific tissues to function normally.

PET can provide unique clinical information in an economically viable manner, resulting in a diagnostic accuracy that affects patient management. PET scans provide diagnostic and prognostic patient information regarding cognitive disorders; for example, identifying the differences between Alzheimer's, Parkinson's, dementia, depression, cerebral disorders, and mild memory loss. PET scans also provide information regarding psychiatric disease, brain tumors, epilepsy, cardiovascular disease, movement disorders, and ataxia. Research shows that clinical PET may obviate the need for other imaging procedures.

PET installations generally take one of two forms: a scanner using only generator-produced tracers (basic PET unit) or a scanner with a cyclotron (enhanced PET unit). The rubidium-82 is the only generator approved by the FDA to produce radiopharmaceuticals. Rubidium limits PET services to cardiac perfusion imaging.

A PET scanner supported by a cyclotron can provide the capabilities for imaging a broader range of PET services, such as oncology, neurology, and cardiology. Manufacturers of PET equipment are providing more user-friendly cyclotrons, radiopharmaceutical delivery systems, and scanners which have drastically reduced personnel and maintenance requirements. These changes have made the cost of PET studies comparable to those of other high-technology studies.

Table XI-4 presents the location, type (fixed or mobile), and utilization of PET equipment throughout the state in 2003. Seventeen hospitals provided a total of 3,146 PET procedures in FY 2003; an additional seven hospitals hold CON authority to provide PET imaging services.

Extracorporeal Shock Wave Lithotripsy (ESWL)

The lithotripter is a medical device which disintegrates kidney or biliary stones (gallstones) by using shock waves. ESWL treatment is noninvasive and therefore avoids surgical intervention. The FDA has approved ESWL for the treatment of kidney stones, but has not approved an ESWL machine for the treatment of biliary stones. Twenty-eight Mississippi hospitals and two free-standing facilities provided renal ESWL services during FY 2003. Four additional hospitals have received CON authority to provide ESWL services. Table XI-5 presents the location, type (fixed or mobile), location, and utilization of renal ESWL equipment by facility by hospital planning areas.

Utilization of ESWL equipment has been considerably less than expected. When first approved, officials estimated that each machine would perform approximately 700 procedures per year. The 30 (hospital based and freestanding) facilities providing the service in 2003 reported an average of only 121 procedures per machine, with a total of 3,629 procedures.

Table XI-4
Location and Number of PET Procedures by General Hospital Service Area
FY 2003

Facility	Location	Type Equipment	Number of PET Procedures
General Hospital Service Area 1			593
Baptist Memorial Hospital - Golden Triangle	Columbus	M	161
Baptist Memorial Hospital - North Mississippi	Oxford	M	257
North Mississippi Medical Center	Tupelo	M	175
General Hospital Service Area 2			220
Baptist Memorial Hospital - DeSoto	Southhaven	M	151
Bolivar Medical Center	Cleveland	M	CON
Delta Regional Medical Center	Greenville	M	CON
Greenwood Leflore Hospital	Greenwood	M	69
General Hospital Service Area 3			1,088
Central Mississippi Medical Center	Jackson	F	302
Mississippi Baptist Medical Center	Jackson	F	613
River Region Health System	Vicksburg	M	CON
St. Dominic Hospital	Jackson	F	107
University Medical Center	Jackson	F	66
General Hospital Service Area 4			247
Jeff Anderson Medical Center	Meridian	M	232
Rush Foundation Hospital	Meridian	M	15
General Hospital Service Area 5			0
Natchez Regional Medical Center	Adams	M	CON
General Hospital Service Area 6			364
Hattiesburg Clinic, P.A.	Hattiesburg	M	204
South Central Regional Medical Center	Laurel	M	84
Wesley Medical Center	Hattiesburg	F	76
General Hospital Service Area 7			634
Biloxi Regional Medical Center	Biloxi	M	CON
Garden Park Medical Center	Gulfport	M	CON
Gulf Coast Medical Center	Biloxi	M	CON
Memorial Hospital at Gulfport	Gulfport	M	318
Ocean Springs Hospital	Ocean Springs	M	72
Singing River Hospital	Pascagoula	M	244
State Total			3,146

F - Fixed Unit

M - Mobile Unit

Source: Applications for Renewal of Hospital License for Calendar Year 2004 and FY 2003 Annual Hospital Report

Table XI-5
Extracorporeal Shock Wave Lithotrispy Utilization
by General Hospital Service Area
FY 2003

Facility	County	Type Equipment	Renal Procedures
General Hospital Service Area 1			735
Baptist Memorial Hospital - Golden Triangle	Lowndes	M	189
Baptist Memorial Hospital - North Mississippi	Lafayette	M	27
Baptist Memorial Hospital - Union County	Union	M	CON
Magnolia Regional Health Center	Alcorn	M	20
North Mississippi Medical Center	Lee	F	460
Oktibbeha County Hospital	Oktibbeha	M	39
General Hospital Service Area 2			178
Baptist Memorial Hospital DeSoto, Inc.	DeSoto	M	11
Bolivar Medical Center	Bolivar	M	CON
Delta Regional Medical Center	Washington	M	52
Greenwood - Leflore Hospital	Leflore	M	71
Northwest Mississippi Regional Medical Center	Coahoma	M	44
General Hospital Service Area 3			1,362
Central Mississippi Medical Center	Hinds	M	244
King's Daughters Hospital (Brookhaven)	Lincoln	M	328
MS Baptist Medical Center	Hinds	M	383
River Region Health System	Warren	M	255
St. Dominic/Jackson Memorial Hospital	Hinds	F/M	72
University Medical Center	Hinds	M	80
General Hospital Service Area 4			217
Jeff Anderson Regional Medical Center	Lauderdale	M	111
Riley Memorial Hospital	Lauderdale	M	40
Rush Foundation Hospital	Lauderdale	M	66
General Hospital Service Area 5			67
Natchez Community Hospital	Adams	M	39
Natchez Regional Medical Center	Adams	M	CON
Southwest Mississippi Regional Medical Center	Pike	F	28
General Hospital Service Area 6			706
Forrest General Hospital	Forrest	M	221
Hattiesburg Clinic, Professional Associates	Forrest	M	280
South Central Regional Medical Center	Jones	M	68
Wesley Medical Center	Lamar	F	137
General Hospital Service Area 7			364
Biloxi Regional Medical Center	Harrison	M	28
Garden Park Medical Center	Harrison	M	CON
Hancock Medical Center	Hancock	M	10
Memorial Hospital at Gulfport	Harrison	M	178
Mississippi Coast Endoscopy Center	Jackson	M	30
Ocean Springs Hospital	Jackson	M	81
Singing River Hospital	Jackson	M	37
State Total			3,629

F - Fixed Unit

M - Mobile Unit

Source: Applications for renewal of Hospital License for Calendar Year 2004 and FY 2003 Annual Hospital Report

Cardiac Catheterization

Cardiac catheterization, predominately a diagnostic tool that is an integral part of cardiac evaluation, brings together two disciplines: cardiac catheterization (the evaluation of cardiac function) and angiography (X-ray demonstration of cardiac anatomy). Cardiac catheterization includes various therapeutic interventions: dilation of coronary obstructions by percutaneous transluminal coronary angioplasty (PTCA), acute lysis of coronary clots in evolving myocardial infarctions by injection of intracoronary streptokinase, electrical ablation of abnormal conduction pathways, and closure of patent ductus arteriosus in infants.

Any facility performing diagnostic cardiac catheterizations without open-heart surgery capability must maintain formal referral agreements with a nearby facility to provide emergency cardiac services, including open-heart surgery. Such a facility must also delineate the steps it will take to ensure that high-risk or unstable patients are not catheterized in the facility. Additionally, a facility without open-heart surgery capability must document that more complex procedures are not performed in the facility. Such procedures include, but are not limited to: PTCA, transseptal puncture, transthoracic left ventricular puncture, and myocardial biopsy.

Note: Percutaneous Transluminal Coronary Angioplasty (PTCA) is an angiographic technique to improve myocardial blood flow by dilating focal atherosclerotic stenoses in coronary arteries. The technique consists of mechanically induced coronary vasodilation and recanalization. It is expected to result in the restoration of blood flow through segmentally diseased coronary arteries. PTCA involves the passage of a balloon-tipped flexible catheter into a site of arterial narrowing. The balloon is inflated in situ to dilate and recanalize the obstructed vessel. Specially trained physicians perform the procedure on hospitalized patients with symptomatic coronary artery disease (CAD) who meet the required patient selection criteria.

Section 41-7-191(1)(d), Mississippi Code of 1972, as amended, requires Certificate of Need review for the establishment and/or offering of cardiac catheterization services if the proposed provider has not offered such services on a regular basis within 12 months prior to the time the services would be offered. Table XI-6 presents the utilization of cardiac catheterization services in 2003.

Open-Heart Surgery

Open-heart surgery, defined as any surgical procedure in which a heart-lung machine is used to maintain cardiopulmonary functioning, involves a number of procedures, including valve replacement, repair of cardiac defects, coronary bypass, heart transplantation, and artificial heart implant.

Section 41-7-191(1)(d), Mississippi Code of 1972, as amended, requires Certificate of Need review for the establishment and/or offering of open-heart surgery services if the proposed provider has not offered such services on a regular basis within 12 months prior to the time the services would be offered.

Table XI-7 presents the utilization of existing facilities. Map XI-2 in the criteria and standards section of this chapter shows the Cardiac Catheterization/Open-Heart Surgery Planning Areas (CC/OHSPAs) and the location of existing services.

Table XI-6
Number of Cardiac Catheterizations by Facility and Type
FY 2002 and FY 2003

Facility	County	Total Adult Procedures		Total Pediatric Procedures		Total PTCA Procedures	
		2002	2003	2002	2003	2002	2003
Baptist Memorial Hospital - DeSoto	DeSoto	1,937	5,600	0	0	416	43
Baptist Memorial Hospital - Golden Triangle	Lowndes	646	450	0	0	102	3
Baptist Memorial Hospital - North MS	Lafayette	1,395	1,006	0	0	255	234
Biloxi Regional Medical Center	Harrison	170	171	0	0	0	0
Central Mississippi Medical Center	Hinds	498	498	0	0	49	49
Delta Regional Medical Center	Washington	2,301	2,648	0	0	360	412
Forrest General Hospital	Forrest	3,352	3,545	0	0	1,126	1,379
Greenwood Leflore Hospital	Leflore	106	31	0	0	0	0
Grenada Lake Medical Center*	Grenada	299	344	0	0	0	0
Jeff Anderson Regional Medical Center	Lauderdale	3,928	1,282	0	0	638	382
Magnolia Regional Health Center	Alcorn	1,124	1,075	0	0	72	119
Memorial Hospital at Gulfport	Harrison	2,998	2,915	0	0	1,919	1,866
Mississippi Baptist Medical Center	Hinds	3,555	3,765	0	0	1,049	1,143
Natchez Regional Medical Center*	Adams	CON	0	0	0	0	0
North Mississippi Medical Center	Lee	6,886	7,353	0	0	1,321	316
Northwest Mississippi Regional Medical Center*	Coahoma	1,527	0	0	0	3	0
Ocean Springs Hospital	Jackson	614	615	0	0	0	0
Rankin Cardiology Center, LLC*●	Rankin	224	127	0	0	0	0
Riley Memorial Hospital**	Lauderdale	312	171	0	0	12	9
River Region Health System	Warren	1,035	1,226	0	0	0	55
Rush Foundation Hospital	Lauderdale	2,119	1,339	0	0	25	334
St. Dominic-Jackson Memorial Hospital	Hinds	2,585	2,366	0	0	765	728
Singing River Hospital	Jackson	730	750	0	0	403	261
South Central Regional Medical Center*	Jones	889	868	0	0	0	0
Southwest Mississippi Regional Medical Center	Pike	0	444	0	0	0	30
University Medical Center	Hinds	2,287	1,835	344	197	335	359
Wesley Medical Center	Lamar	1,187	1,077	0	0	579	439
Total		42,704	41,501	344	197	9,429	8,161

*Diagnostic Catheterizations only

**Performed by Jeff Anderson Regional Medical Center

●Provides Diagnostic Cardiac Catheterizations for Rankin Medical Center, Women's Hospital, and River Oaks Hospital patients, at River Oaks Hospital Campus

Sources: Applications for Renewal of Hospital License for Calendar Years 2003 and 2004, and Fiscal Years 2002 and 2003 Annual Hospital Reports, CON files

Table XI-7
Number of Open-Heart Surgeries by Facility and Type
FY 2002 and FY 2003

Facility	County	Number of Adult Open-Heart Procedures		Number of Pediatric Open-Heart Procedures		Number of Pediatric Heart Procedures (Excluding Open-Heart)	
		2002	2003	2002	2003	2002	2003
Baptist Memorial Hospital - DeSoto	Desoto	241	219	0	0	0	0
Baptist Memorial Hospital - Golden Triangle	Lowndes	53	35	0	0	0	0
Baptist Memorial Hospital - North MS	Lafayette	239	143	0	0	0	0
Central Mississippi Medical Center	Hinds	91	93	0	0	0	0
Delta Regional Medical Center	Washington	109	41	0	0	0	0
Forrest General Hospital	Forrest	518	701	0	0	0	0
Greenwood Leflore Hospital	Leflore	0	0	—	0	0	0
Jeff Anderson Regional Medical Center	Lauderdale	300	276	0	0	0	0
Memorial Hospital at Gulfport	Harrison	426	320	0	0	0	0
Mississippi Baptist Medical Center	Hinds	383	341	0	0	0	0
North Mississippi Medical Center	Lee	906	940	0	0	0	0
Ocean Springs Hospital	Jackson	0	60	0	0	0	0
River Region Health System	Warren	CON	33	0	0	0	0
Rush Foundation Hospital	Lauderdale	41	52	0	0	0	0
St. Dominic-Jackson Memorial Hospital	Hinds	651	612	0	0	0	0
Singing River Hospital	Jackson	170	160	0	0	0	0
Southwest Miss. Regional Medical Center	Pike	0	20	0	0	0	0
University Medical Center	Hinds	173	203	20	18	32	19
Wesley Medical Center	Lamar	141	59	0	0	0	0
Total		4,442	4,308	20	18	32	19

Sources: Applications for Renewal of Hospital License for Calendar Years 2003 and 2004, and Fiscal Years 2002 and 2003 Annual Hospital Reports, CON Files

**Certificate of Need
Criteria and Standards
for
Acute Care**

Should the Mississippi State Department of Health receive a Certificate of Need application regarding the acquisition and/or otherwise control of major medical equipment or the provision of a service for which specific CON criteria and standards have not been adopted, the application shall be deferred until the Department of Health has developed and adopted CON criteria and standards. If the Department has not developed CON criteria and standards within 180 days of receiving a CON application, the application will be reviewed using the general CON review criteria and standards presented in the *Mississippi Certificate of Need Review Manual* and all adopted rules, procedures, and plans of the Mississippi State Department of Health.

Policy Statement Regarding Certificate of Need Applications for General Acute Care Hospitals and General Acute Care Beds

1. Acute Care Hospital Need Methodology: With the exception of psychiatric, chemical dependency, and rehabilitation hospitals, the Mississippi State Department of Health (MSDH) will use the following methodologies to project the need for general acute care hospitals:
 - a. **Counties Without a Hospital** - The MSDH shall determine hospital need by multiplying the state's average annual occupied beds (1.85 in FY 2003) per 1,000 population by the estimated 2005 county population to determine the number of beds the population could utilize. A hospital with a maximum of 100 beds may be considered for approval if: (a) the number of beds needed is 100 or more; (b) there is strong community support for a hospital; and (c) a hospital can be determined to be economically feasible.
 - b. **Counties With Existing Hospitals** - The MSDH shall use the following formula to determine the need for an additional hospital in a county with an existing hospital:
$$ADC + K(\sqrt{ADC})$$

Where:
ADC = Average Daily Census
K = Confidence Factor of 2.57

The formula is calculated for each facility within a given General Hospital Service Area (GHSA); then beds available and beds needed under the statistical application of the formula are totaled and subtracted to determine bed need or excess within each GHSA. Map XI-1 delineates the GHSAs. The MSDH may consider approval of a hospital with a maximum of 100 beds if: (a) the number of beds needed is 100 or more; (b) there is strong community support for a hospital; and (c) a hospital can be determined to be economically feasible.
2. Need in Counties Without a Hospital: Nine counties in Mississippi do not have a hospital: Amite, Benton, Carroll, Greene, Issaquena, Itawamba, Kemper, Smith, and Tunica. Most of these counties do not have a sufficient population base to indicate a potential need for the establishment of a hospital, and all appear to receive sufficient inpatient acute care services from hospitals in adjoining counties.
3. Expedited Review: The MSDH may consider an expedited review for Certificate of Need applications that address only license code deficiencies, project cost overruns, and relocation of facilities or services.
4. Capital Expenditure: For the purposes of Certificate of Need review, transactions which are separated in time but planned to be undertaken within 12 months of each other and which are components of an overall long-range plan to meet patient care objectives shall be reviewed in their entirety without regard to their timing. For the purposes of this policy, the governing board of the facility must have duly adopted the long-range plan at least 12 months prior to the submission of the CON application.
5. Effective April 12, 2002, no health care facility shall be authorized to add any beds or convert any beds to another category of beds without a Certificate of Need.

Certificate of Need Criteria and Standards for the Establishment of a General Acute Care Hospital

The Mississippi State Department of Health (MSDH) will review applications for a Certificate of Need to construct, develop, or otherwise establish a new hospital under the applicable statutory requirements of Sections 41-7-173, 41-7-191, and 41-7-193, Mississippi Code of 1972, as amended. The MSDH will also review applications for Certificate of Need according to the general criteria listed in the *Mississippi Certificate of Need Review Manual*; all adopted rules, procedures, and plans of the MSDH; and the specific criteria and standards listed below.

1. **Need Criterion: The applicant shall document a need for a general acute care hospital using the appropriate need methodology as presented in this section of the *Plan*. In addition, the applicant must meet the other conditions set forth in the need methodology.**
2. The application shall document that the applicant will provide a "reasonable amount" of indigent/charity care as described in Chapter I of this *Plan*.

Certificate of Need Criteria and Standards for Construction, Renovation, Expansion, Capital Improvements, Replacement of Health Care Facilities, and Addition of Hospital Beds

The Mississippi State Department of Health (MSDH) will review applications for a Certificate of Need for the addition of beds to a health care facility and projects for construction, renovation, expansion, or capital improvement involving a capital expenditure in excess of \$2,000,000 under the applicable statutory requirements of Sections 41-7-173, 41-7-191, and 41-7-193, Mississippi Code of 1972, as amended. The MSDH will also review applications for Certificate of Need according to the general criteria listed in the *Mississippi Certificate of Need Review Manual*; all adopted rules, procedures, and plans of the (MSDH); and the specific criteria and standards listed below.

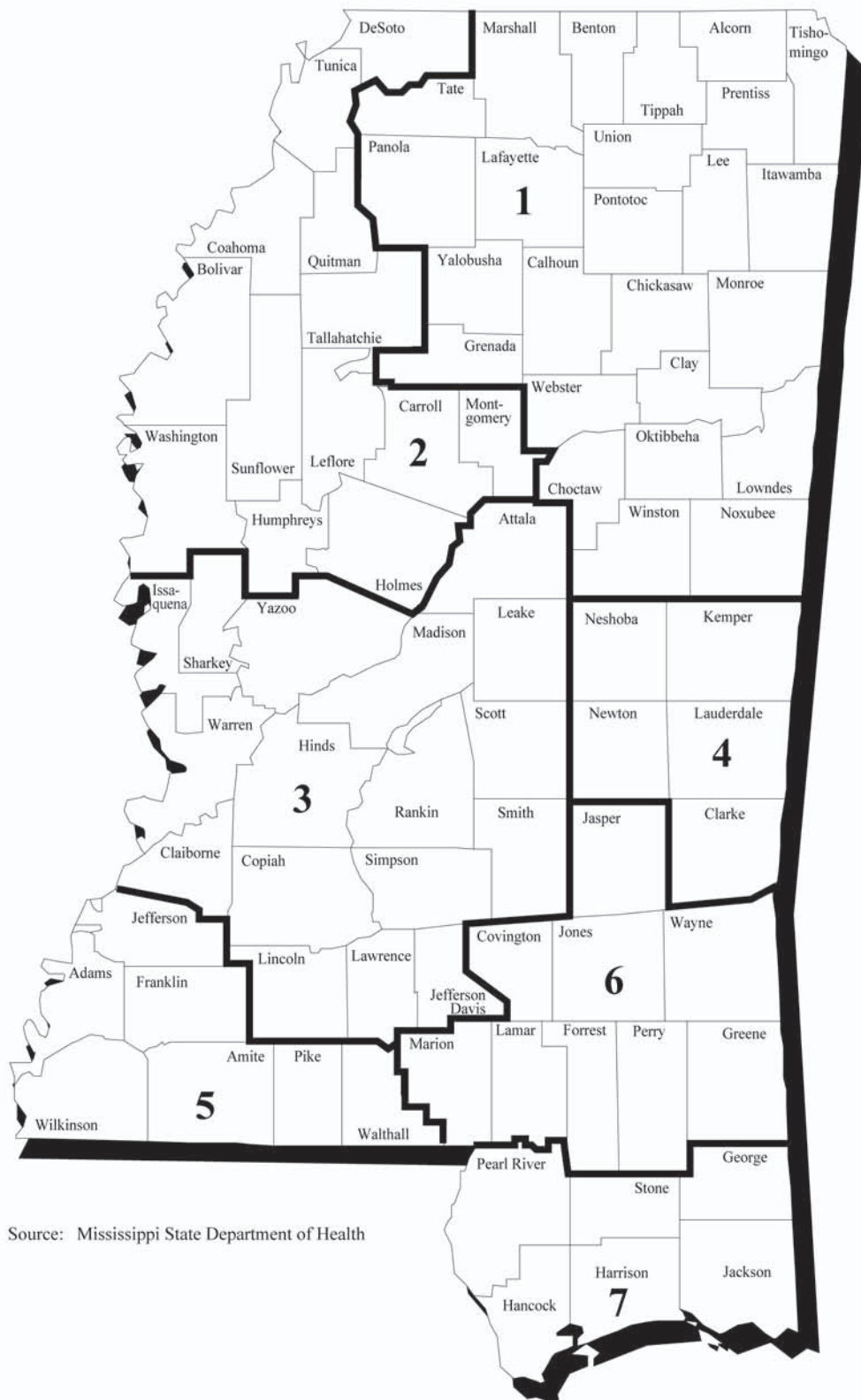
The construction, development, or other establishment of a new health care facility; the replacement and/or relocation of a health care facility or portion thereof; and changes of ownership of existing health care facilities are reviewable regardless of capital expenditure.

1. **Need Criterion:**
 - a. **Projects which do not involve the addition of any acute care beds:** The applicant shall document the need for the proposed project. Documentation may consist of, but is not limited to, citing of licensure or regulatory code deficiencies, institutional long-term plans (duly adopted by the governing board), recommendations made by consultant firms, and deficiencies cited by accreditation agencies (JCAHO, CAP, etc.). In addition, for projects which involve construction, renovation, or expansion of emergency department facilities, the applicant shall include a statement indicating whether the hospital will participate in the statewide trauma system and describe the level of participation, if any.
 - b. **Projects which involve the addition of beds:** The applicant shall document the need for the proposed project. In addition to the documentation required as stated in Need Criterion (1)(a), the applicant shall document that the facility in question

has maintained an occupancy rate of at least 70 percent for the most recent two (2) years.

2. Bed Service Transfer/Reallocation/Relocation: Applications proposing the transfer, reallocation, and/or relocation of a specific category or sub-category of bed/service from another facility as part of a renovation, expansion, or replacement project shall document that the applicant will meet all regulatory/licensure requirements for the type of bed/service being transferred/reallocated/relocated.
3. Charity/Indigent Care: The application shall affirm that the applicant will provide a "reasonable amount" of indigent/charity care as described in Chapter I of this *Plan*.
4. The application shall demonstrate that the cost of the proposed project, including equipment, is reasonable in comparison with the cost of similar projects in the state.
 - a. The applicant shall document that the cost per square foot (per bed if applicable) does not exceed the median construction costs, as determined by the MSDH, for similar projects in the state within the most recent 12-month period by more than 15 percent. The Glossary of this *Plan* provides the formulas to be used by MSDH staff in calculating the cost per square foot for construction and/or construction/renovation projects.
 - b. If equipment costs for the project exceed the median costs for equipment of similar quality by more than 15 percent, the applicant shall provide justification for the excessive costs. The median costs shall be based on projects submitted during the most recent six-month period and/or estimated prices provided by acceptable vendors.
5. The applicant shall specify the floor areas and space requirements, including the following factors:
 - a. The gross square footage of the proposed project in comparison to state and national norms for similar projects.
 - b. The architectural design of the existing facility if it places restraints on the proposed project.
 - c. Special considerations due to local conditions.
6. If the cost of the proposed renovation or expansion project exceeds 85 percent of the cost of a replacement facility, the applicant shall document their justification for rejecting the option of replacing said facility.
7. The applicant shall document the need for a specific service (i.e. perinatal, ambulatory care, psychiatric, etc.) using the appropriate service specific criteria as presented in this and other sections of the *Plan*.

Map XI-1 General Hospital Service Areas



Source: Mississippi State Department of Health

Certificate of Need Criteria and Standards for Swing-Bed Services

The Mississippi State Department of Health will review applications for a Certificate of Need to establish swing-bed services under the applicable statutory requirements of Sections 41-7-173, 41-7-191, and 41-7-193, Mississippi Code of 1972, as amended. The MSDH will also review applications for Certificate of Need according to the general criteria listed in the *Mississippi Certificate of Need Review Manual*; all adopted rules, procedures, and plans of the Mississippi State Department of Health; and the specific criteria and standards listed below.

1. **Need Criterion: The application shall document that the hospital will meet all federal regulations regarding the swing-bed concept.** However, a hospital may have more licensed beds or a higher average daily census (ADC) than the maximum number specified in federal regulations for participation in the swing-bed program.

The applicant shall provide a copy of the Resolution adopted by its governing board approving the proposed participation.

2. If the applicant proposes to operate and staff more than the maximum number of beds specified in federal regulations for participation in the swing-bed program, the application shall give written assurance that only private pay patients will receive swing-bed services.
3. The application shall affirm that upon receiving CON approval and meeting all federal requirements for participation in the swing-bed program, the applicant shall render services provided under the swing-bed concept to any patient eligible for Medicare (Title XVIII of the Social Security Act) who is certified by a physician to need such services.
4. The application shall affirm that upon receiving CON approval and meeting all federal requirements for participation in the swing-bed program, the applicant shall not permit any patient who is eligible for both Medicaid and Medicare or is eligible only for Medicaid to stay in the swing-beds of a hospital for more than 30 days per admission unless the hospital receives prior approval for such patient from the Division of Medicaid, Office of the Governor.
5. The application shall affirm that if the hospital has more licensed beds or a higher average daily census (ADC) than the maximum number specified in federal regulations for participation in the swing-bed program, the applicant will develop a procedure to ensure that, before a patient is allowed to stay in the swing-beds of the hospital, there are no vacant nursing home beds available for that patient within a 50-mile radius (geographic area) of the hospital. The applicant shall also affirm that if the hospital has a patient staying in the swing-beds of the hospital and the hospital receives notice from a nursing home located within a 50-mile radius that there is a vacant bed available for that patient, the hospital shall transfer the swing-bed patient to the nursing home within five days, exclusive of holidays and weekends, unless the patient's physician certifies that the transfer is not medically appropriate.

The applicant shall provide copies of transfer agreements entered into with each nursing facility within the applicant's geographic area.

6. An applicant subject to the conditions stated in Criterion #5 shall affirm in the application that they will be subject to suspension from participation in the swing-bed program for a reasonable period of time by the State Department of Health if the Department, after a hearing complying with due process, determines that the hospital has failed to comply with any of those requirements.

**Certificate of Need
Criteria and Standards
for
Therapeutic Radiation Services**

Should the Mississippi State Department of Health receive a Certificate of Need application regarding the acquisition and/or otherwise control of major medical equipment or the provision of a service for which specific CON criteria and standards have not been adopted, the application shall be deferred until the Department of Health has developed and adopted CON criteria and standards. If the Department has not developed CON criteria and standards within 180 days of receiving a CON application, the application will be reviewed using the general CON review criteria and standards presented in the *Mississippi Certificate of Need Review Manual* and all adopted rules, procedures, and plans of the Mississippi State Department of Health.

**Policy Statement Regarding Certificate of Need Applications
for the Acquisition or Otherwise Control of Therapeutic Radiation
Equipment and/or the Offering of Therapeutic Radiation Services
(Other Than Gamma Knife)**

1. Service Areas: The Mississippi State Department of Health shall determine the need for therapeutic radiation services/units/equipment by using the General Hospital Service Areas as presented in this chapter of the *Plan*. The MSDH shall determine the need for therapeutic radiation services/units/equipment within a given service area independently of all other service areas. Map XI-1 shows the General Hospital Service Areas.
2. Equipment to Population Ratio: The need for therapeutic radiation units (as defined) is determined to be one unit per 170,200 population (see methodology in this section of the *Plan*). The MSDH will consider out-of-state population in determining need only when the applicant submits adequate documentation acceptable to the Mississippi State Department of Health, such as valid patient origin studies.
3. Limitation of New Services: When the therapeutic radiation unit-to-population ratio reaches one to 170,200 in a given general hospital service area, no new therapeutic radiation services may be approved unless the utilization of all the existing machines in a given hospital service area averaged 8,000 treatment procedures or 320 patients per year for the two most recent consecutive years as reported on the "Renewal of Hospital License and Annual Hospital Report." For the purposes of this policy Cesium-137 teletherapy units, Cobalt-60 teletherapy units designed for use at less than 80 cm SSD (source to skin distance), old betatrons and van de Graaf Generators, unsuitable for modern clinical use, shall not be counted in the inventory of therapeutic radiation units located in a hospital service area.
4. Expansion of Existing Services: The MSDH may consider a CON application for the acquisition or otherwise control of an additional therapeutic radiation unit by an existing provider of such services when the applicant's existing equipment has exceeded the expected level of patient service, i.e., 320 patients per year or 8,000 treatments per year for the two most recent consecutive years as reported on the facility's "Renewal of Hospital Licenses and Annual Hospital Report."
5. Equipment Designated for Backup: Therapeutic radiation equipment designated by an applicant as "backup" equipment shall not be counted in the inventory for CON purposes. Any procedures performed on the "backup" equipment shall be attributed to the primary equipment for CON purposes.
6. Definition of a Treatment Procedure: For health planning and CON purposes a patient "treatment" is defined as one individual receiving radiation therapy during a visit to a facility which provides megavoltage radiation therapy regardless of the complexity of the procedure or the number of "fields" treated during the visit.
7. Use of Equipment or Provision of Service: Before the equipment or service can be utilized or provided, the applicant desiring to provide the therapeutic radiation equipment or service shall have CON approval or written evidence that the equipment or service is exempt from CON approval, as determined by the Mississippi State Department of Health.

Certificate of Need Criteria and Standards for the Acquisition

**or Otherwise Control of Therapeutic Radiation Equipment
and/or the Offering of Therapeutic Radiation Services
(Other Than Gamma Knife)**

The Mississippi State Department of Health will review Certificate of Need applications for the acquisition or otherwise control of therapeutic radiation equipment and/or the offering of therapeutic radiation services under the applicable statutory requirements of Sections 41-7-173, 41-7-191, and 41-7-193, Mississippi Code of 1972, as amended. The MSDH will also review applications for Certificate of Need according to the general criteria listed in the *Mississippi Certificate of Need Review Manual*; all adopted rules, procedures, and plans of the Mississippi State Department of Health; and the specific criteria and standards listed below.

The acquisition or otherwise control of therapeutic radiation equipment is reviewable if the equipment cost exceeds \$1,500,000. The offering of therapeutic radiation services is reviewable if the proposed provider has not provided those services on a regular basis within the period of twelve (12) months prior to the time such services would be offered.

1. **Need Criterion: The applicant shall document a need for therapeutic radiation equipment/service by complying with any one of the following methodologies:**
 - (a) the need methodology as presented in this section of the *Plan*;
 - (b) demonstrating that all existing machines in the service area in question have averaged 8,000 procedures per year or all machines have treated an average of 320 patients per year for the two most recent consecutive years; or
 - (c) demonstrating that the applicant's existing therapeutic equipment has exceeded the expected level of patients service, i.e. 320 patients per year/unit, or 8,000 treatments per year/unit for the most recent 24-month period; or
 - (d) demonstrating to the satisfaction of the MSDH staff that the applicant (i) is a hospital having a minimum of 175 licensed acute care beds as of January 1, 2001; (ii) is located more than a forty (40) mile radius from an existing provider of therapeutic radiation services; and (iii) has the patient base needed to sustain a viable therapeutic radiation program, as defined by the Therapeutic Radiation Need Methodology. Policy Criterion # 3 does not apply to this Need Criterion #1 (d).
2. The applicant must document that access to diagnostic X-ray, CT scan, and ultrasound services is readily available within 15 minutes normal driving time of the therapeutic radiation unit's location.
3. An applicant shall document the following:
 - a. The service will have, at a minimum, the following full-time dedicated staff:
 - 1) One board-certified radiation oncologist-in-chief
 - 2) One dosimetrist
 - 3) One certified radiation therapy technologist certified by the American Registry of Radiation Technologists

4) One registered nurse

- b. The service will have, at a minimum, access to a radiation physicist certified or eligible for certification by the American Board of Radiology.

Note: One individual may act in several capacities. However, the application shall affirm that when a staff person acts in more than one capacity, that staff person shall meet, at a minimum, the requirements for each of the positions they fill.

- 4. The applicant shall affirm that access will be available as needed to brachytherapy staff, treatment aides, social workers, dietitians, and physical therapists.
- 5. Applicants shall document that all physicians who are responsible for therapeutic radiation services in a facility, including the radiation oncologist-in-chief, shall reside within 60 minutes normal driving time of the facility.
- 6. The application shall affirm that the applicant will have access to a modern simulator capable of precisely producing the geometric relationships of the treatment equipment to a patient. This simulator must produce high quality diagnostic radiographs. The applicant shall also affirm that the following conditions will be met as regards the use of the simulator:
 - a. If the simulator is located at a site other than where the therapeutic radiation equipment is located, protocols will be established which will guarantee that the radiation oncologist who performs the patient's simulation will also be the same radiation oncologist who performs the treatments on the patient.
 - b. If the simulator uses fluoroscopy, protocols will be established to ensure that the personnel performing the fluoroscopy have received appropriate training in the required techniques related to simulation procedures.

Note: X-rays produced by diagnostic X-ray equipment and photon beams produced by megavoltage therapy units are unsuitable for precise imaging of anatomic structures within the treatment volume and do not adequately substitute for a simulator.

- 7. The application shall affirm that the applicant will have access to a computerized treatment planning system with the capability of simulation of multiple external beams, display isodose distributions in more than one plane, and perform dose calculations for brachytherapy implants.

Note: It is highly desirable that the system have the capability of performing CT based treatment planning.

- 8. The applicant shall affirm that all treatments will be under the control of a board certified or board eligible radiation oncologist.
- 9. The applicant shall affirm that the proposed site, plans, and equipment shall receive approval from the Division of Radiological Health before service begins.
- 10. The application shall affirm that the applicant will establish a quality assurance program for the service, as follows:

- a. The therapeutic radiation program shall meet, at a minimum, the physical aspects of quality assurance guidelines established by the American College of Radiology (ACR) within 12 months of initiation of the service.
 - b. The service shall establish a quality assurance program which meets, at a minimum, the standards established by the American College of Radiology.
11. The applicant shall affirm understanding and agreement that failure to comply with criterion #10 (a) and (b) may result in revocation of the CON (after due process) and subsequent termination of authority to provide therapeutic radiation services.

Therapeutic Radiation Equipment/Service Need Methodology

The methodology used to project the need for therapeutic radiation equipment/service is based, generally, upon recommendations of the 1990 Therapeutic Radiation Task Force and the guidelines contained in the publication *Radiation Oncology in Integrated Cancer Management*, a report of the Inter-Society Council for Radiation Oncology published in 1986. The publication is more commonly referred to as the "Blue Book."

- a. Treatment/Patient Load: A realistic treatment/patient load for a therapeutic radiation unit is 8,000 treatments or 320 patients per year.
- b. Incidence of Cancer: The Cancer Registry of the Mississippi State Department of Health estimates that Mississippi will experience 12,408 new cancer patients in 2004. Based on a population of 2,991,488 (year 2005) as estimated by the Center for Policy Research and Planning, the cancer rate of Mississippi is 4.15 cases per 1,000 population.
- c. Patients to Receive Treatment: The number of cancer patients expected to receive therapeutic radiation treatment is set at 45 percent.
- d. Population to Equipment Ratio: Using the above stated data, a population of 100,000 will generate 415 new cancer cases each year. Assuming that 45 percent will receive radiation therapy, a population of 171,360 will generate approximately 320 patients who will require radiation therapy. Therefore, a population of 171,360 will generate a need for one therapeutic radiation unit.

Therapeutic Radiation Equipment Need Determination Formula

1. Project annual number of cancer patients.

$$\frac{\text{General Hospital Service Area Population}}{1,000 \text{ population}} \times \frac{4.15 \text{ cases}^*}{1,000 \text{ population}} = \text{New Cancer Cases}$$

*Mississippi cancer incidence rate

2. Project the annual number of radiation therapy patients.

$$\text{New Cancer Cases} \times 45\% = \text{Patients Who Will Likely Require Radiation Therapy}$$

3. Estimate number of procedures to be performed annually.

$$\text{Radiation Therapy Patients} \times 25 \text{ Procedures Per Patient (Avg.)} = \text{Estimated Number of Procedures}$$

4. Project number of megavoltage radiation therapy units needed.

$$\frac{\text{Est. \# of Procedures}}{8,000 \text{ Procedures Per Unit}} = \text{Projected Number of Units Needed}$$

5. Determine unmet need (if any). $\text{Projected Number of Units Needed} - \text{Number of Existing Units} = \text{Number of Units Required (Excess)}$

**Policy Statement Regarding Certificate of Need Applications
for the Acquisition or Otherwise Control of Gamma Knife Therapeutic
Radiation Equipment and/or the Offering of Gamma Knife Therapeutic
Radiation Services**

1. Service Areas: The Mississippi State Department of Health shall determine the need for Gamma Knife intracranial stereotactic radiosurgery services/units/equipment by using the state as a whole as a single state Gamma Knife service area.
2. Equipment to Population Ratio: The need for Gamma Knife therapeutic radiation units is determined to be one unit per 2,800,000 population. The MSDH will consider out-of-state population in determining need only when the applicant submits adequate documentation acceptable to the Mississippi State Department of Health, such as valid patient origin studies. The Gamma Knife will not be included in the inventory of other therapeutic radiation treatment equipment, and the presence of a Gamma Knife will not be used in the determination of the need for other therapeutic radiation equipment, such as additional linear accelerators.
3. Accessibility: The state's population will limit the availability of Gamma Knives to one. The single Gamma Knife should be located in or near a Jackson hospital with close associations with the University of Mississippi School of Medicine and the University Medical Center. Nothing contained in these CON criteria and standards shall preclude the University of Mississippi School of Medicine from acquiring and operating Gamma Knife therapeutic radiation equipment, provided the acquisition and use of such equipment is justified by the School's teaching and/or research mission. However, the requirements listed under the section regarding the granting of "appropriate scope of privileges for access to the Gamma Knife equipment to any qualified physician" must be met.
4. Expansion of Existing Services: The MSDH may consider a CON application for the acquisition or otherwise control of an additional therapeutic radiation unit by an existing provider of such services when the applicant's existing equipment has exceeded the expected level of patient service, i.e., 200 patients per year for the two most recent consecutive years as reported on the facility's "Renewal of Hospital Licenses and Annual Hospital Report."
5. Facilities requesting approval to add Gamma Knife services should have an established neurosurgery program and must be able to demonstrate previous radiosurgery service experience.
6. All Gamma Knife surgery services should have written procedures and policies for discharge planning and follow-up care for the patient and family as part of the institution's overall discharge planning program.
7. All Gamma Knife surgery services should have established protocols for referring physicians to assure adequate post-operative diagnostic evaluation for radiosurgery patients.
8. The total cost of providing Gamma Knife surgery services projected by prospective providers should be comparable to the cost of other similar services provided in the state.
9. The usual and customary charge to the patient for Gamma Knife surgery should be commensurate with cost.

Certificate of Need Criteria and Standards for the Acquisition or Otherwise Control of Gamma Knife Therapeutic Radiation Equipment and/or the Offering of Gamma Knife Radiosurgery

The Mississippi State Department of Health will review Certificate of Need applications for the acquisition or otherwise control of Gamma Knife radiosurgery equipment and/or the offering of Gamma Knife radiosurgery services under the applicable statutory requirements of Sections 41-7-173, 41-7-191, and 41-7-193, Mississippi Code of 1972, as amended. The MSDH will also review applications for Certificate of Need according to the general criteria listed in the *Mississippi Certificate of Need Review Manual*; all adopted rules, procedures, and plans of the Mississippi State Department of Health; and the specific criteria and standards listed below.

The acquisition or otherwise control of Gamma Knife radiosurgery equipment is reviewable if the equipment cost exceeds \$1,500,000. The offering of Gamma Knife radiosurgery services is reviewable if the proposed provider has not provided those services on a regular basis within the period of twelve (12) months prior to the time such services would be offered.

1. **Need Criterion: The applicant shall document a need for Gamma Knife radiosurgery equipment/service by reasonably projecting that the proposed new service will perform at least 200 Gamma Knife surgeries in the third year of operation. No additional new Gamma Knife surgery services should be approved unless the number of surgeries performed with existing units in the state average more than 475 per year.**
2. **Staffing:**
 - a. The Gamma Knife surgery programs must be established under the medical direction of two co-directors, one with specialty training and board certification in neurosurgery and the other with specialty training and board certification in radiation oncology, with experience in all phases of Gamma Knife surgical procedures.
 - b. In addition to the medical co-directors, all Gamma Knife surgery programs should have a radiation physicist who is certified in radiology, or who holds an advanced degree in physics with two to three years experience working under the direction of a radiation oncologist, and a registered nurse present for each Gamma Knife surgery performed.
 - c. The applicant shall document that the governing body of the entity offering Gamma Knife therapeutic radiation services will grant an appropriate scope of privileges for access to the Gamma Knife therapeutic radiation equipment to any qualified physician who applies for privileges. For the purpose of this criterion, "Qualified Physician" means a doctor of medicine or osteopathic medicine licensed by the State of Mississippi who possesses training in Gamma Knife intracranial stereotactic radiosurgery and other qualifications established by the governing body.
3. **Equipment:**

- a. Facilities providing Gamma Knife surgery services should have dosimetry and calibration equipment and a computer with the appropriate software for performing Gamma Knife surgery.
- b. The facility providing Gamma Knife surgery services should also have access to magnetic resonance imaging, computed tomography, and angiography services.

**Certificate of Need
Criteria and Standards
for
Diagnostic Imaging Services**

Should the Mississippi State Department of Health receive a Certificate of Need application regarding the acquisition and/or otherwise control of major medical equipment or the provision of a service for which specific CON criteria and standards have not been adopted, the application shall be deferred until the Department of Health has developed and adopted CON criteria and standards. If the Department has not developed CON criteria and standards within 180 days of receiving a CON application, the application will be reviewed using the general CON review criteria and standards presented in the *Mississippi Certificate of Need Review Manual* and all adopted rules, procedures, and plans of the Mississippi State Department of Health.

**Policy Statement Regarding Certificate of Need Applications for
the Acquisition or Otherwise Control of Magnetic Resonance
Imaging (MRI) Equipment and/or the Offering of MRI Services**

1. CON Review Requirements: The Certificate of Need process regarding the acquisition or otherwise control of MRI equipment and/or the offering of MRI services involves separate requirements for CON review: (a) an entity proposing to acquire or otherwise control MRI equipment must obtain a CON to do so if the capital expenditure for the MRI unit and related equipment exceeds \$1,500,000; and (b) an entity proposing to offer MRI services must obtain a CON before providing such services.
2. CON Approval Preference: The Mississippi State Department of Health shall give preference to those applicants proposing to enter into joint ventures utilizing mobile and/or shared equipment. However, the applicant must meet the applicable CON criteria and standards provided herein and the general criteria and standards contained in the currently approved *Mississippi Certificate of Need Review Manual*.
3. Procedures Estimation Methodology: The applicant shall use the procedures estimation methodology appearing in this section of the *Plan* to project the annual patient service volume for MRI services/equipment. The DRG disease classification system to be used for MRI is available from the Mississippi State Department of Health Division of Health Planning and Resource Development.
4. Addition of a Health Care Facility: An equipment vendor who proposes to add a health care facility to an existing or proposed route must obtain an amendment to the original Certificate of Need before providing such service. Additionally, an equipment vendor must inform the Department of any proposed changes, i.e. additional health care facilities or route deviations, from those presented in the Certificate of Need application prior to such change.

Certificate of Need Criteria and Standards for the Acquisition or Otherwise Control of Magnetic Resonance Imaging (MRI) Equipment and/or the Offering of MRI Services

The Mississippi State Department of Health will review applications for a Certificate of Need for the acquisition or otherwise control of MRI equipment and/or the offering of MRI services under the applicable statutory requirements of Sections 41-7-173, 41-7-191, and 41-7-193, Mississippi Code of 1972, as amended. The MSDH will also review applications for Certificate of Need according to the general criteria listed in the *Mississippi Certificate of Need Review Manual*; all adopted rules, procedures, and plans of the Mississippi State Department of Health; and the specific criteria and standards listed below.

The acquisition or otherwise control of MRI equipment is reviewable if the equipment cost is in excess of \$1,500,000; if the equipment and/or service is relocated; and if the proposed provider of MRI services has not provided such services on a regular basis within the period of twelve (12) months prior to the time such services would be offered.

Certificate of Need Criteria and Standards for the Acquisition or Otherwise Control of MRI Equipment

1. **Need Criterion: The entity desiring to acquire or otherwise control the MRI equipment must document that the specified equipment shall perform a minimum of 1,700 procedures per year by the end of the second year of operation. The applicant shall use the procedures estimation methodology appearing in this section of the *Plan* to project the annual patient service volume of the proposed equipment. This criterion includes both fixed and mobile MRI equipment.**

It is recognized that an applicant desiring to acquire or otherwise control an MRI unit may make or propose to make the MRI unit available to more than one provider of MRI services; some of which may be located outside of Mississippi. In such cases all existing or proposed users of the MRI unit must jointly meet the required service volume of 1,700 procedures annually. If the MRI unit in question is presently utilized by other providers of MRI services, the actual number of procedures performed by them during the most recent 12-month period may be used instead of the formula projections.

2. In order to receive CON approval to acquire or otherwise control MRI equipment, the applicant shall provide a copy of the proposed contract and document the following:
 - a. that the equipment is FDA approved;
 - b. that only qualified personnel will be allowed to operate the equipment; and
 - c. that if the equipment is to be rented, leased, or otherwise used by other qualified providers on a contractual basis, no fixed/minimum volume contracts will be permitted.
3. Applicants shall provide written assurance that they will record and maintain, at a minimum, the following information and make it available to the Mississippi State Department of Health:
 - a. all facilities which have access to the equipment;

- b. utilization by each facility served by the equipment, e.g., days of operation, number of procedures, and number of repeat procedures;
- c. financial data, e.g., copy of contracts, fee schedule, and cost per scan; and
- d. demographic and patient origin data for each facility.

In addition, if required by the Department, the above referenced information and other data pertaining to the use of MRI equipment will be made available to the MSDH within 15 business days of request. The required information may also be requested for entities outside of Mississippi that use the MRI equipment in question.

- 4. The entity desiring to acquire or otherwise control the MRI equipment must be a registered entity authorized to do business in Mississippi.
- 5. Before the specified equipment can be utilized, the applicant desiring to provide the MRI equipment shall have CON approval or written evidence that the equipment is exempt from CON approval, as determined by the Mississippi State Department of Health. Each specified piece of equipment must be exempt from or have CON approval.

Certificate of Need Criteria and Standards for the Offering of MRI Services

An entity proposing to offer MRI services shall obtain Certificate of Need (CON) approval before offering such services.

- 1. **Need Criterion: The entity desiring to offer MRI services must document that the equipment shall perform a minimum of 1,700 procedures per year. The applicant shall use the procedures estimation methodology appearing in this section of the *Plan* to project the annual patient service volume for the applicant hospital. This criterion includes both fixed and mobile MRI equipment.**

It is recognized that a particular MRI unit may be utilized by more than one provider of MRI services; some of which may be located outside of Mississippi. In such cases all existing or proposed providers of MRI services must jointly meet the required service volume of 1,700 procedures annually. If the MRI unit in question is presently utilized by other providers of MRI services, the actual number of procedures performed by them during the most recent 12-month period may be used instead of the formula projections.

- 2. An applicant desiring to offer MRI services must document that a full range of diagnostic imaging modalities for verification and complementary studies will be available at the time MRI services begin. These modalities shall include, but not be limited to, computed tomography (full body), ultrasound, angiography, nuclear medicine, and conventional radiology.
- 3. All applicants proposing to offer MRI services shall give written assurance that, within the scope of its available services, neither the facility where the service is provided nor its participating medical personnel shall have policies or procedures which would exclude patients because of race, color, age, sex, ethnicity, or ability to pay.
- 4. The applicant must document that the following staff will be available:

- a. Director - A full-time, board eligible radiologist or nuclear medicine imaging physician, or other board eligible licensed physician whose primary responsibility during the prior three years has been in the acquisition and interpretation of clinical images. The Director shall have a knowledge of MRI through training, experience, or documented post-graduate education. The Director shall document a minimum of one week of full-time training with a functional MRI facility.
 - b. One full-time MRI technologist-radiographer or a person who has had equivalent education, training, and experience, who shall be on-site at all times during operating hours. This individual must be experienced in computed tomography or other cross-sectional imaging methods, or must have equivalent training in MRI spectroscopy.
- 5. The applicant shall document that when an MRI unit is to be used for experimental procedures with formal/approved protocols, a full-time medical physicist or MRI scientist (see definition in Glossary) with at least one year of experience in diagnostic imaging shall be available in the facility.
- 6. The applicant shall provide assurances that the following data regarding its use of the MRI equipment will be kept and made available to the Mississippi State Department of Health upon request:
 - a. Total number of procedures performed
 - b. Number of inpatient procedures
 - c. Number of outpatient procedures
 - d. Average MRI scanning time per procedure
 - e. Average cost per procedure
 - f. Average charge per procedure
 - g. Demographic/patient origin data
 - h. Days of operation

In addition to the above data recording requirements, the facility should maintain the source of payment for procedures and the total amounts charged during the fiscal year when it is within the scope of the recording system.

- 7. Before the service can be provided, the CON applicant desiring to offer MRI services shall provide written evidence that the specified MRI equipment provider has received CON approval or is exempt from CON approval as determined by the Mississippi State Department of Health. Each specified piece of equipment must be exempt from or have CON approval.

Procedures Estimation Methodology for MRI Equipment

MRI patient service volume shall be based on a DRG disease classification system of all inpatients of the hospital, other participating hospitals, and the number of outpatients in receipt of CT scans from the respective hospitals. Under this system, the DRGs are classified and ranked in relation to the expected applicability of MRI imaging. Diagnoses for which MRI imaging is not likely to be useful in current application fall into Category 1. Category 2 includes those diagnoses for which MRI imaging may be a useful secondary imaging modality in some cases. Category 3 encompasses diagnoses for which MRI is likely to be a useful secondary imaging modality. Category 4 includes those diagnoses for which MRI is expected to be the primary imaging modality. The listing of DRG categories to be used in establishing the need for MRI services may be obtained from the Mississippi State Department of Health Division of Health Planning and Resource Development.

First, the methodology classifies the total number of inpatient admissions into the four categories. The admission total for each category is zero, five, 15, and 50 percent, respectively. This derives the estimated number of inpatients most likely to benefit from MRI services. Secondly, the methodology identifies the total number of outpatients referred for CT scanning during the previous fiscal year. A 25 percent utilization factor is applied to that total in order to derive the number of outpatients most likely to benefit from MRI imaging. Inpatient and outpatient estimates are summed to derive the total MRI volume for the first year of operation. The mathematical formula for calculating volume estimates is as follows:

$$EC = .50 (TN_4) + .15 (TN_3) + .05 (TN_2) + .25 (TN_{ct})$$

Where:

EC = Estimated MRI patient service volume for the first or next year of operation.

TN₄ = Total number of inpatient hospital admissions in DRG Category 4 for the preceding fiscal year.

TN₃ = Total number of inpatient hospital admissions in DRG Category 3 for the preceding fiscal year.

TN₂ = Total number of inpatient hospital admissions in DRG Category 2 for the preceding fiscal year.

TN_{ct} = Total number of outpatients who received CT scans for the preceding fiscal year.

If the hospital projects a greater number of procedures for the end of the second year than the formula estimates, this projection must be based on the actual increases in the number of diagnoses within each category over the past three years.

Certificate of Need Criteria and Standards for Digital Subtraction Angiography

The Mississippi State Department of Health will review applications for a Certificate of Need for the acquisition or otherwise control of Digital Subtraction Angiography (DSA) equipment and associated costs under the applicable statutory requirements of Sections 41-7-173, 41-7-191, and 41-7-193, Mississippi Code of 1972, as amended. The MSDH will also review applications for Certificate of Need according to the general criteria listed in the *Mississippi Certificate of Need Review Manual*; all adopted rules, procedures, and plans of the Mississippi State Department of Health; and the specific criteria and standards listed below.

Certificate of Need review is required when the capital expenditure for the purchase of Digital Subtraction Angiography equipment and associated costs exceed \$1,500,000, or when the equipment is to be used for invasive procedures, i.e., the use of catheters. The offering of diagnostic imaging services of an invasive nature, i.e. invasive digital angiography, is reviewable if those services have not been provided on a regular basis by the proposed provider of such services within the period of twelve (12) months prior to the time such services would be offered.

- 1. Need Criterion: The applicant for DSA services shall demonstrate that proper protocols for screening, consultation, and medical specialty backup are in place before services are rendered by personnel other than those with specialized training.**

For example, if a radiologist without specialized training in handling cardiac arrhythmia is to perform a procedure involving the heart, a cardiologist/cardiosurgeon must be available for consultation/backup.

The protocols shall include, but are not limited to, having prior arrangements for consultation/backup from:

- 1) a cardiologist/cardiosurgeon for procedures involving the heart;
 - 2) a neurologist/neurosurgeon for procedures involving the brain; and
 - 3) a vascular surgeon for interventional peripheral vascular procedures.
2. Before utilizing or providing the equipment or service, the applicant desiring to provide the digital subtraction angiography equipment or service shall have CON approval or written evidence that the equipment or service is exempt from CON approval as determined by the Mississippi State Department of Health.

**Policy Statement Regarding Certificate of Need Applications
for the Acquisition or Otherwise Control of a
Positron Emission Tomography (PET) Scanner and
Related Equipment**

1. CON Review Requirements: Applicants proposing the acquisition or otherwise control of a PET scanner shall obtain a CON to do so if the capital expenditure for the scanner and related equipment exceeds \$1,500,000.
2. Indigent/Charity Care: An applicant shall be required to provide a "reasonable amount" of indigent/charity care as described in Chapter I of this *Plan*.
3. Service Areas: The state as a whole shall serve as a single service area in determining the need for a PET scanner.
4. Equipment to Population Ratio: The need for a PET scanner is estimated to be one scanner per 300,000 population. The MSDH will consider out-of-state population in determining need only when the applicant submits adequate documentation acceptable to the MSDH, such as valid patient origin studies.
5. Access to Supplies: Applicants must have direct access to appropriate radio-pharmaceuticals.
6. Services and Medical Specialties Required: The proposed PET unit must function as a component of a comprehensive inpatient or outpatient diagnostic service. The proposed PET unit must have the following modalities (and capabilities) on-site or through contractual arrangements:
 - 1) Computed tomography - (whole body);
 - 2) Magnetic resonance imaging - (brain and whole body);
 - 3) Nuclear medicine - (cardiac, SPECT);
 - 4) Conventional radiography; and
 - 5) The following medical specialties during operational hours:
 - a. Cardiology,
 - b. Neurology,
 - c. Neurosurgery,
 - d. Oncology,
 - e. Psychiatry, and
 - f. Radiology.
7. Hours of Operation: PET facilities should have adequate scheduled hours to avoid an excessive backlog of cases.
8. CON Approval Preference: The MSDH may approve applicants proposing to enter joint ventures utilizing mobile and/or shared equipment.
9. CON Requirements: The criteria and standards contained herein pertain to both fixed and/or mobile PET scanner equipment.
10. CON Exemption: Nothing contained in these CON criteria and standards shall preclude the University of Mississippi School of Medicine from acquiring and operating a PET scanner,

provided the acquisition and use of such equipment is justified by the School's teaching and/or research mission. However, the requirements listed under the section regarding the granting of "appropriate scope of privileges for access to the scanner to any qualified physician" must be met. The MSDH shall not consider utilization of equipment/services at any hospital owned and operated by the state or its agencies when reviewing CON applications.

11. Addition to a Health Care Facility: An equipment vendor who proposes to add a health care facility to an existing or proposed route must amend the original Certificate of Need before providing such service. Additionally, an equipment vendor must inform the Department of any proposed changes from those presented in the Certificate of Need application prior to such change, i.e., additional health care facilities or route deviations.
12. Equipment Registration: The applicant must provide the Department with the registration/serial number of the CON-approved PET scanner.
13. Certification: If a mobile PET scanner, the applicant must certify that only the single authorized piece of equipment and related equipment vendor described in the CON application will be utilized for the PET service by the authorized facility/facilities.

Certificate of Need Criteria and Standards for the Acquisition or Otherwise Control of a Positron Emission Tomography (PET) Scanner and Related Equipment

The Mississippi State Department of Health will review applications for a Certificate of Need for the acquisition or otherwise control of a PET scanner and related equipment under the applicable statutory requirements of Sections 41-7-173, 41-7-191, and 41-7-193, Mississippi Code of 1972, as amended. The MSDH will also review applications for Certificate of Need according to the general review criteria listed in the *Mississippi Certificate of Need Review Manual*; all adopted rules, procedures, and plans of the Mississippi State Department of Health; and the specific criteria and standards listed below.

The acquisition or otherwise control of a PET scanner and related equipment is reviewable if the equipment cost is in excess of \$1,500,000, or if the equipment is relocated. The offering of PET services is reviewable if the proposed provider has not provided those services on a regular basis within the period of twelve (12) months prior to the time such services would be offered.

1. **Need Criterion:**
 - a. **The entity desiring to acquire or to otherwise control the PET scanner must project a minimum of 750 clinical procedures per year and must show the methodology used for the projection.**
 - b. **The applicant shall document a minimum population of 300,000 per PET scanner unit. The Division of Health Planning and Resource Development population projections shall be used.**
2. The entity desiring to acquire or otherwise control the PET equipment must be a registered entity authorized to do business in Mississippi.
3. The MSDH will approve additional PET equipment in an area with existing equipment only when it is demonstrated that the existing PET equipment is performing 1,500 clinical procedures per PET unit per year (six clinical procedures per day x 250 working days per year).
4. An applicant proposing to provide new or expanded PET services must include written assurances in the application that the service will be offered in a physical environment that conforms to federal standards, manufacturer's specifications, and licensing agencies' requirements. The following areas are to be addressed:
 - a. quality control and assurance of radiopharmaceutical production of generator or cyclotron-produced agents;
 - b. quality control and assurance of PET tomograph and associated instrumentation;
 - c. radiation protection and shielding; and
 - d. radioactive emissions to the environment.
5. The application shall affirm that the applicant shall receive approval from the Division of Radiological Health for the proposed site, plans, and equipment before service begins.

6. The applicant shall document provision of an on-site medical cyclotron for radionuclide production and a chemistry unit for labeling radiopharmaceuticals; or an on-site rubidium-82 generator; or access to a supply of cyclotron-produced radiopharmaceuticals from an off-site medical cyclotron and a radiopharmaceutical production facility within a two-hour air transport radius.
7. The applicant must provide evidence that the proposed PET equipment has been cleared for marketing by the U.S. Food and Drug Administration or will be operated under an institutional review board whose membership is consistent with U.S. Department of Health and Human Services regulations.
8. Applicants for PET shall document that the necessary qualified staff are available to operate the proposed unit. The applicant shall document the PET training and experience of the staff. The following minimum staff shall be available to the PET unit:
 - a. One or more nuclear medicine imaging physician(s) available to the PET unit on a full-time basis (e.g., radiologist, nuclear cardiologist) who have been licensed by the state for the handling of medical radionuclides and whose primary responsibility for at least a one-year period prior to submission of the Certificate of Need application has been in acquisition and interpretation of tomographic images. This individual shall have knowledge of PET through training, experience, or documented postgraduate education. The individual shall also have training with a functional PET facility.
 - b. If operating a cyclotron on site, a qualified PET radiochemist or radiopharmacist personnel, available to the facility during PET service hours, with at least one year of training and experience in the synthesis of short-lived positron emitting radiopharmaceuticals. The individual(s) shall have experience in the testing of chemical, radiochemical, and radionuclidic purity of PET radiopharmaceutical syntheses.
 - c. Qualified engineering and physics personnel, available to the facility during PET service hours, with training and experience in the operation and maintenance of the PET equipment.
 - d. Qualified radiation safety personnel, available to the facility at all times, with training and experience in the handling of short-lived positron emitting nuclides. If a medical cyclotron is operated on-site, personnel with expertise in radiopharmacy, radiochemistry, and medical physics would also be required.
 - e. Certified nuclear medicine technologists with expertise in computed tomographic nuclear medicine imaging procedures, at a staff level consistent with the proposed center's expected PET service volume.
 - f. Other appropriate physicians shall be available during PET service hours which may include certified nuclear medicine technologists, computer programmers, nurses, and radio-chemistry technicians.
9. The applicant shall demonstrate how medical emergencies within the PET unit will be managed in conformity with accepted medical practice.

10. The applicant shall affirm that, in addition to accepting patients from participating institutions, facilities performing clinical PET procedures shall accept appropriate referrals from other local providers. These patients shall be accommodated to the extent possible by extending the hours of service and by prioritizing patients according to standards of need and appropriateness rather than source of referral.
11. The applicant shall affirm that protocols will be established to assure that all clinical PET procedures performed are medically necessary and cannot be performed as well by other, less expensive, established modalities.
12. Applicants will be required to maintain current listings of appropriate PET procedures for use by referring physicians.
13. The applicant shall provide assurances that the following data regarding the PET equipment will be kept and made available to the Mississippi State Department of Health upon request:
 - a. total number of procedures performed;
 - b. total number of inpatient procedures (indicate type of procedure);
 - c. total number of outpatient procedures (indicate type of procedure);
 - d. average charge per specific procedure;
 - e. hours of operation of the PET unit;
 - f. days of operation per year; and
 - g. total revenues and expenses for the PET unit for the year.
14. The applicant shall provide a copy of the proposed contract and document that if the equipment is to be rented, leased, or otherwise used by other qualified providers on a contractual basis, no fixed/minimum volume contracts will be permitted.
15. Before the specified equipment can be utilized, the applicant desiring to provide the PET equipment shall have CON approval or written evidence that the equipment is exempt from CON approval as determined by the Mississippi State Department of Health. Each specified piece of equipment must be exempt from or have CON approval.

**Certificate of Need
Criteria and Standards
for
Extracorporeal Shock Wave
Lithotripsy
(ESWL)**

Should the Mississippi State Department of Health receive a Certificate of Need application regarding the acquisition and/or otherwise control of major medical equipment or the provision of a service for which specific CON criteria and standards have not been adopted, the application shall be deferred until the Department of Health has developed and adopted CON criteria and standards. If the Department has not developed CON criteria and standards within 180 days of receiving a CON application, the application will be reviewed using the general CON review criteria and standards presented in the *Mississippi Certificate of Need Review Manual* and all adopted rules, procedures, and plans of the Mississippi State Department of Health.

Policy Statement Regarding Certificate of Need Applications for the Acquisition or Otherwise Control of Extracorporeal Shock Wave Lithotripsy (ESWL) Equipment and/or the Offering of ESWL Services

1. CON Review Requirements: The Certificate of Need (CON) process regarding acquisition or otherwise control of ESWL equipment and/or the offering of ESWL services involves separate requirements for CON review: a) an entity proposing to acquire or otherwise control ESWL equipment shall obtain a CON to do so if the capital expenditure for the ESWL unit and related equipment exceeds \$1,500,000; and b) an entity proposing to offer ESWL services shall obtain a CON before providing such services.
2. CON Approval Preference: The MSDH shall give preference to applicants proposing to enter joint ventures utilizing mobile and/or shared equipment. However, the applicant must meet the applicable CON criteria and standards provided herein and the general criteria and standards contained in the currently approved *Mississippi Certificate of Need Review Manual*.
3. The criteria and standards contained herein pertain to both fixed and/or mobile ESWL equipment and/or services.
4. Nothing contained in these CON criteria and standards shall preclude the University of Mississippi School of Medicine from acquiring and operating ESWL equipment, provided the acquisition and use of such equipment is justified by the School's teaching and/or research mission. However, the requirements listed under the section regarding the granting of "appropriate scope of privileges for access to the lithotripter to any qualified physician" must be met.
5. The requirements for the provision of services for Medicaid, Medicare, and medically indigent patients, as they appear in this section, also apply to the provision of Renal and Biliary ESWL services through the use of dual capability machines.
6. Addition of a Health Care Facility: An equipment vendor who proposes to add a health care facility to an existing or proposed route must obtain an amendment to the original Certificate of Need before providing such service. Additionally, an equipment vendor must inform the Department of any proposed changes, i.e. additional health care facilities or route deviations, from those presented in the Certificate of Need application prior to such change.

Certificate of Need Criteria and Standards for the Acquisition or Otherwise Control of Extracorporeal Shock Wave Lithotripsy (ESWL) Equipment and/or the Offering of ESWL Services

The Mississippi State Department of Health will review applications for a Certificate of Need for the acquisition or otherwise control of ESWL equipment and/or the offering of ESWL services under the applicable statutory requirements of Sections 41-7-173, 41-7-191, and 41-7-193, Mississippi Code of 1972, as amended. The MSDH will also review applications for Certificate of Need according to the general criteria listed in the *Mississippi Certificate of Need Review Manual*; all adopted rules, procedures, and plans of the Mississippi State Department of Health; and the specific criteria and standards listed below.

The acquisition or otherwise control of ESWL equipment is reviewable if the equipment cost exceeds \$1,500,000. The offering of ESWL services is reviewable if the proposed provider has

not provided those services on a regular basis within the period of twelve (12) months prior to the time such services would be offered.

Certificate of Need Criteria and Standards for the Acquisition or Otherwise Control of Renal ESWL Equipment

1. **Need Criterion: The entity desiring to acquire or otherwise control the Renal ESWL equipment must document that the specified equipment shall perform a minimum of 300 procedures a year.**

It is recognized that an applicant desiring to acquire or otherwise control a Renal ESWL unit may make or propose to make the Renal ESWL unit available to more than one provider of Renal ESWL services; some of which may be located outside of Mississippi. In such cases all existing or proposed utilizers of the Renal ESWL unit must jointly meet the required service volume of 300 procedures annually. If the Renal ESWL unit in question is presently utilized by other providers of Renal ESWL services, the actual number of procedures performed by them during the most recent 12-month period may be used.

2. In order to receive CON approval to acquire or otherwise control Renal ESWL equipment, the applicant shall provide a copy of the proposed contract and document the following:
 - a. that the equipment is FDA approved;
 - b. that only qualified personnel will be allowed to operate the equipment; and
 - c. that if the equipment is to be rented, leased, or otherwise used by other qualified providers on a contractual basis, no fixed/minimum volume contracts will be permitted.
3. Applicants shall provide written assurance that they will record and maintain, at a minimum, the following information and make it available to the Mississippi State Department of Health:
 - a. all facilities which have access to the equipment;
 - b. utilization by each facility served by the equipment, e.g., days of operation, number of procedures, and number of repeat procedures;
 - c. financial data, e.g., copy of contracts and fee schedule, and cost per scan; and
 - d. demographic and patient origin data for each facility.

Additionally, if required by the Department, the above referenced information and other data pertaining to the use of Renal ESWL equipment shall be made available to the MSDH within 15 business days of request. The above required information may be requested for entities outside Mississippi that use the Renal ESWL equipment in question.

4. The entity desiring to acquire or otherwise control the Renal ESWL equipment must be a registered entity authorized to do business in Mississippi.
5. Before the specified equipment can be utilized, the applicant desiring to provide the Renal ESWL equipment shall have CON approval or written evidence that the equipment is

exempt from CON approval as determined by the Mississippi State Department of Health. Each specified piece of equipment must be exempt from or have CON approval.

Certificate of Need Criteria and Standards for the Offering of Renal ESWL Services

An entity proposing to offer Renal ESWL services shall obtain Certificate of Need approval before offering such services,

1. **Need Criterion: An applicant proposing to offer Renal ESWL services must project a minimum utilization of three procedures per month for 12 months per year (36 procedures per year) using the methodology stated below.**

- a. Projections of the number of procedures the equipment is expected to perform shall be based on historical utilization of equipment during the most recent fiscal year and/or the projected number of procedures expected to be performed. The applicant shall use the following methodology to project the expected number of procedures:

Methodology: The projected number of procedures shall be equal to the number of historical referrals of patients with renal calculi for Renal ESWL to other facilities which offer Renal ESWL during the most recent fiscal year.

- b. An applicant proposing a shared unit involving two or more qualified facilities and/or proposing to offer Renal ESWL services to other facilities must provide documentation that identifies the number of referrals from each facility. The applicant must also provide affiliation and/or transfer agreements to validate the numbers of patients who potentially will utilize the Renal ESWL services.
- c. Because some applicants will be unable to perform a minimum of three Renal ESWL procedures per month during the early months of providing Renal ESWL services, the MSDH may issue a conditional CON to applicants projecting fewer than three procedures per month. Applicants granted a conditional CON shall report to the MSDH, at six month intervals from the time the Renal ESWL services are commenced, the number of procedures performed during the most recent six-month period. If the utilization at the close of the 18th month is fewer than three procedures per month, the MSDH shall revoke the CON for failure to meet the minimum utilization deemed necessary to maintain an acceptable level of proficiency.

2. All applicants proposing to offer Renal ESWL services must document that the following medical personnel have staff privileges and are available to provide emergency services following Renal ESWL treatment at the facility where the applicant will offer the services:

- a. Board certified general surgeon;
- b. Board certified urologist; and
- c. Board certified radiologist with experience in X-ray, CT, and ultrasound imaging.

The above referenced medical personnel shall reside within the hospital service area and shall be available 24 hours per day for emergency services required as a result of treatment by Renal ESWL.

3. Applicants proposing to offer Renal ESWL services must have whole body CT scanner capability and ultrasound imaging capability.
4. The applicant shall document that the governing body of the entity offering Renal ESWL services will grant an appropriate scope of privileges for access to the lithotripter to any qualified physician who applies for privileges. For the purpose of this criterion, "Qualified Physician" means a doctor of medicine or osteopathic medicine licensed by the State of Mississippi who possesses training in Renal ESWL and other qualifications established by the governing body.
5. The applicant shall document the extent to which Medicare, Medicaid, and medically indigent patients are being or will be offered access to Renal ESWL services. An applicant shall be disapproved for failing to document that they will offer a "reasonable amount" of indigent care or for having admission policies which will adversely affect access to care for indigents.
6. Applicants shall offer written assurance that they will record and maintain, at a minimum, the following information and make it available to the Mississippi State Department of Health:
 - a. utilization data, e.g., days of operation, number of procedures, and number of repeat procedures;
 - b. demographic/patient origin data;
 - c. cost/charges data, e.g., cost/charges per procedure;
 - d. any other data pertaining directly or indirectly to the use of the Renal ESWL equipment and/or the treatment of urinary calculi; and
 - e. data regarding surgical removal of urinary calculi.

Additionally, if required by the Department, the above referenced information and any other data pertaining to the use of Renal ESWL service or equipment will be made available to the Mississippi State Department of Health within 15 business days of request.

7. The CON application must document an active radiology service and an established urological referral practice.
8. The CON applicant must document in the application that all individuals using the equipment shall meet, at a minimum, the American Urological Association's guidelines and standards for training and proficiency in the operation of Renal ESWL equipment.
9. Before providing the service, the applicant desiring to offer Renal ESWL services shall provide written evidence that the specified Renal ESWL equipment provider has received CON approval or is exempt from CON approval as determined by the Mississippi State Department of Health. Each specified piece of equipment must be exempt from or have CON approval.

**Certificate of Need Criteria and Standards for the Acquisition
or Otherwise Control of Biliary ESWL Equipment**

1. **Need Criterion: The entity desiring to acquire or otherwise control the Biliary ESWL equipment must document that the specified equipment shall perform a minimum of 300 procedures per year.**

It is recognized that an applicant desiring to acquire or otherwise control a Biliary ESWL unit may make or propose to make the Biliary ESWL unit available to more than one provider of Biliary ESWL services; some of which may be located outside of Mississippi. In such cases all existing or proposed utiliziers of the Biliary ESWL unit must jointly meet the required service volume of 300 procedures annually. If the Biliary ESWL unit in question is presently utilized by other providers of Biliary ESWL services, the actual number of procedures performed by them during the most recent 12-month period may be used.

2. In order to receive CON approval to acquire or otherwise control Biliary ESWL equipment, the applicant shall provide a copy of the proposed contract and document the following:
 - a. that the equipment is FDA approved;
 - b. that only qualified personnel will be allowed to operate the equipment; and
 - c. that if the equipment is to be rented, leased, or otherwise used by other qualified providers on a contractual basis, no fixed/minimum volume contracts will be permitted.
3. Applicants shall provide written assurance that they will record and maintain, at a minimum, the following information and make it available to the Mississippi State Department of Health:
 - a. all facilities which have access to the equipment;
 - b. utilization by each facility served by the equipment, e.g., days of operation, number of procedures, and number of repeat procedures; and
 - c. financial data, e.g., copy of contracts and fee schedule.

Additionally, if required by the Department, the above referenced information and other data pertaining to the use of Biliary ESWL equipment shall be made available to the MSDH within 15 business days of request.

The above required information may be requested for entities outside of Mississippi that use the Biliary ESWL equipment in question.

4. The entity desiring to acquire or otherwise control Biliary ESWL equipment must be a registered entity authorized to do business in Mississippi.
5. Before utilizing the specified equipment, the applicant desiring to provide the Biliary ESWL equipment shall have CON approval or written evidence that the specified equipment is exempt from CON approval as determined by the Mississippi State Department of Health. Each specified piece of equipment must be exempt from or have CON approval.

Certificate of Need Criteria and Standards for the Offering of Biliary ESWL Services

An entity proposing to offer Biliary ESWL services shall obtain Certificate of Need approval before offering such services.

1. Need Criterion: An applicant proposing to offer Biliary ESWL services must project a minimum utilization of three procedures per month for 12 months per year (36 procedures per year) using the methodology stated below.

- a. Projections of the number of procedures the equipment is expected to perform shall be based on historical utilization of equipment during the most recent fiscal year and/or the projected number of procedures expected to be performed. The applicant shall use the following methodology to project the expected number of procedures:

Methodology: Twenty-five (25) percent of all patients who have received cholecystectomies may have been candidates for treatment with Biliary ESWL. Therefore, when projecting the number of procedures an applicant expects to perform, 25 percent of the cholecystectomies performed in the participating facility(ies) during the most recent fiscal year will count as the number of Biliary ESWL procedures expected to be performed at the facility.

- b. An applicant proposing a shared unit involving two or more qualified facilities and/or proposing to provide Biliary ESWL services to other facilities must provide documentation that identifies the number of referrals from each facility. The applicant must also provide affiliation and/or transfer agreements to validate the numbers of patients who potentially will utilize the Biliary ESWL services.
- c. Because some applicants will be unable to perform a minimum of three Biliary ESWL procedures per month during the early months of providing Biliary ESWL services, the MSDH may issue a conditional CON to applicants projecting fewer than three procedures per month. Applicants granted a conditional CON shall report to the Department, at six-month intervals from the time the Biliary ESWL services are commenced, the number of procedures performed during the most recent six-month period. If the utilization at the close of the 18th month is fewer than three procedures per month, the MSDH shall revoke the CON for failure to meet the minimum utilization deemed necessary to maintain an acceptable level of proficiency.

2. All applicants proposing to offer Biliary ESWL services must document that the following medical personnel have staff privileges and are available to provide emergency services following Biliary ESWL treatment at the facility where the services are to be offered:

- a. Board certified general surgeon;
- b. Board certified gastroenterologist; and
- c. Board certified radiologist with experience in X-ray, CT, and ultrasound imaging.

The above referenced medical personnel shall reside within the hospital service area and shall be available 24 hours per day for emergency services required as a result of treatment by Biliary ESWL.

3. Applicants proposing to offer Biliary ESWL services must have the following physical equipment:
 - a. Gastroenterology laboratory;
 - b. Endoscopic retrograde cholangiopancreatography capability; and
 - c. Whole body CT scanner capability and ultrasound imaging capability.
4. The applicant shall document that the governing body of the entity offering Biliary ESWL services will grant an appropriate scope of privileges for access to the lithotripter to any qualified physician who applies for privileges. For the purpose of this criterion, "Qualified Physician" means a doctor of medicine or osteopathic medicine licensed by the State of Mississippi who possesses training in Biliary ESWL and other qualifications established by the governing body.
5. The applicant shall document the extent to which Medicare, Medicaid, and medically indigent patients are being or will be provided access to Biliary ESWL services. An applicant shall be disapproved for failing to document that they will provide a "reasonable amount" of indigent care or for having admission policies which will adversely affect access to care for indigents.
6. Applicants shall provide written assurance that they will record and maintain, at a minimum, the following information and make it available to the Mississippi State Department of Health in the form of an *Annual Report*:
 - a. utilization data, e.g., days of operation, number of procedures, and number of repeat procedures;
 - b. demographic/patient origin data;
 - c. cost/charges data, e.g., cost/charges per procedure;
 - d. any other data pertaining directly or indirectly to the use of the Biliary ESWL equipment and/or the treatment of cholelithiasis; and
 - e. data regarding cholecystectomies.

Additionally, if required by the Department, the above referenced information and any other data pertaining to the use of Biliary ESWL service or equipment will be made available to the Mississippi State Department of Health within 15 business days of request.

7. Before providing the service, the applicant desiring to offer Biliary ESWL services shall provide written evidence that the Biliary ESWL equipment provider has received CON approval or is exempt from CON approval as determined by the Mississippi State Department of Health. Each specified piece of equipment must be exempt from or have CON approval.

**Certificate of Need Criteria and Standards
for Dual Capability ESWL Equipment, i.e.,
Renal/Biliary ESWL Equipment**

1. **Need Criterion: An applicant proposing to offer Renal and Biliary ESWL services through the use of dual capability ESWL equipment must meet both the equipment utilization requirements for Renal ESWL services and Biliary ESWL services.**
2. Providers proposing to offer both Renal and Biliary ESWL services, through the use of dual capability equipment, must also document that they will meet the applicable staffing and physical requirements listed under the Renal and Biliary ESWL Certificate of Need criteria and standards section of this *Plan* before providing such ESWL services.
3. Entities authorized to offer Renal ESWL services who also desire to provide Biliary ESWL services through an FDA approved upgrading of existing equipment must document that they will meet the applicable staffing and physical requirements for providing Biliary ESWL services as contained herein.
4. Before providing the service, the applicant desiring to offer Renal and Biliary ESWL services shall provide written evidence that the dual capability equipment provider has received CON approval or is exempt from CON approval as determined by the Mississippi State Department of Health. Each specified piece of equipment must be exempt from or have CON approval.

**Certificate of Need
Criteria and Standards
for
Long-Term Care Hospitals/Beds**

Should the Mississippi State Department of Health receive a Certificate of Need application regarding the acquisition and/or otherwise control of major medical equipment or the provision of a service for which specific CON criteria and standards have not been adopted, the application shall be deferred until the Department of Health has developed and adopted CON criteria and standards. If the Department has not developed CON criteria and standards within 180 days of receiving a CON application, the application will be reviewed using the general CON review criteria and standards presented in the *Mississippi Certificate of Need Review Manual* and all adopted rules, procedures, and plans of the Mississippi State Department of Health.

Policy Statement Regarding Certificate of Need Applications for Long-Term Care Hospitals and Long-Term Care Hospital Beds

1. Restorative Care Admissions: Restorative care admissions shall be identified as patients with one or more of the following conditions or disabilities:
 - a. Neurological Disorders
 - (1) Head Injury
 - (2) Spinal Cord Trauma
 - (3) Perinatal Central Nervous System Insult
 - (4) Neoplastic Compromise
 - (5) Brain Stem Trauma
 - (6) Cerebral Vascular Accident
 - (7) Chemical Brain Injuries
 - b. Central Nervous System Disorders
 - (1) Motor Neuron Diseases
 - (2) Post Polio Status
 - (3) Developmental Anomalies
 - (4) Neuromuscular Diseases (e.g. Multiple Sclerosis)
 - (5) Phrenic Nerve Dysfunction
 - (6) Amyotrophic Lateral Sclerosis
 - c. Cardio-Pulmonary Disorders
 - (1) Obstructive Diseases
 - (2) Adult Respiratory Distress Syndrome
 - (3) Congestive Heart Failure
 - (4) Respiratory Insufficiency
 - (5) Respiratory Failure
 - (6) Restrictive Diseases
 - (7) Broncho-Pulmonary Dysplasia
 - (8) Post Myocardial Infarction
 - (9) Central Hypoventilation
 - d. Pulmonary Cases
 - (1) Presently Ventilator-Dependent/Weanable
 - (2) Totally Ventilator-Dependent/Not Weanable
 - (3) Requires assisted or partial ventilator support
 - (4) Tracheostomy that requires supplemental oxygen and bronchial hygiene
2. Bed Licensure: All beds designated as long-term care hospital beds shall be licensed as general acute care.
3. Average Length of Stay: Patients' average length of stay in a long-term care hospital must be 25 days or more.

4. Size of Facility: Establishment of a long-term care hospital shall not be for less than 20 beds.
5. Long-Term Medical Care: A long-term care hospital shall provide chronic or long-term medical care to patients who do not require more than three (3) hours of rehabilitation or comprehensive rehabilitation per day.
6. Transfer Agreement: A long-term care hospital shall have a transfer agreement with an acute care medical center and a comprehensive medical rehabilitation facility.
7. Effective July 1, 1994, no health care facility shall be authorized to add any beds or convert any beds to another category of beds without a Certificate of Need under the authority of Section 41-7-191(1)(c), unless there is a projected need for such beds in the planning district in which the facility is located.

Certificate of Need Criteria and Standards for the Establishment of a Long-Term Care Hospital and Addition of Long-Term Care Hospital Beds

The Mississippi State Department of Health will review applications for a Certificate of Need for the construction, development, or otherwise establishment of a long-term care hospital and bed additions under the applicable statutory requirements of Sections 41-7-173, 41-7-191, and 41-7-193, Mississippi Code of 1972, as amended. The MSDH will also review applications for Certificate of Need according to the general criteria listed in the *Mississippi Certificate of Need Review Manual*; all adopted rules, procedures, and plans of the Mississippi State Department of Health; and the specific criteria and standards listed below.

1. **Need Criterion: The applicant shall document a need for the proposed project. Documentation shall consist of the following:**
 - a. **a minimum of 450 clinically appropriate restorative care admissions with an average length of stay of 25 days; and**
 - b. **a projection of financial feasibility by the end of the third year of operation.**
2. The applicant shall document that any beds which are constructed/converted will be licensed as general acute care beds offering long-term care hospital services.
3. Applicants proposing the transfer/reallocation/relocation of a specific category or sub-category of bed/service from another facility as part of a renovation, expansion, or replacement project shall document that they will meet all regulatory and licensure requirements for the type of bed/service proposed for transfer/reallocation/relocation.
4. The application shall affirm that the applicant will provide a "reasonable amount" of indigent/charity care as described in Chapter I of this *Plan*.
5. The application shall demonstrate that the cost of the proposed project, including equipment, is reasonable in comparison with the cost of similar projects in the state.

The applicant shall document that the cost per square foot (per bed if applicable) does not exceed the median construction costs, as determined by the MSDH, for similar projects in the state within the most recent 12-month period by more than 15 percent.

The Glossary of this *Plan* provides the formulas MSDH staff shall use to calculate the cost per square foot of space for construction and/or construction-renovation projects.

6. The applicant shall specify the floor areas and space requirements, including the following factors:
 - a. The gross square footage of the proposed project in comparison to state and national norms for similar projects.
 - b. The architectural design of the existing facility if it places restraints on the proposed project.
 - c. Special considerations due to local conditions.
7. The applicant shall provide copies of transfer agreements entered into with an acute care medical center and a comprehensive medical rehabilitation facility.

**Certificate of Need
Criteria and Standards
for
Cardiac Catheterization Services
and
Open-Heart Surgery Services**

Should the Mississippi State Department of Health receive a Certificate of Need application regarding the acquisition and/or otherwise control of major medical equipment or the provision of a service for which specific CON criteria and standards have not been adopted, the application shall be deferred until the Department of Health has developed and adopted CON criteria and standards. If the Department has not developed CON criteria and standards within 180 days of receiving a CON application, the application will be reviewed using the general CON review criteria and standards presented in the *Mississippi Certificate of Need Review Manual* and all adopted rules, procedures, and plans of the Mississippi State Department of Health.

**Joint Policy Statement Regarding Certificate of Need Applications
for the Acquisition or Otherwise Control
of Cardiac Catheterization Equipment
and/or the Offering of Cardiac Catheterization Services
and the Acquisition of Open-Heart Surgery Equipment
and/or the Offering of Open-Heart Surgery Services**

Mississippi ranks first in the nation in cardiovascular death rate. Heart disease remains the leading cause of death in the state as incidence rates continue to increase, particularly among the African Americans population. Studies show that minorities have a higher cardiovascular death rate than whites and are less likely to receive cardiac catheterization and open-heart surgery services than are whites. The disproportionate impact on minorities' health status in general is recognized elsewhere in this *State Health Plan*.

Innovative approaches to address these problems in the cardiac area are needed. It has been shown that statistical methods, such as population base and optimum capacity at existing providers, are not accurate indicators of the needs of the underserved, nor do they address the accessibility of existing programs to the underserved. The goal of these revisions to the *State Health Plan* is to improve access to cardiac care and to encourage the establishment of additional cardiac catheterization and open-heart surgery programs within the state that can serve the poor, minorities, and the rural population in greater numbers.

To further this goal, the MSDH adopted the following standards:

1. A minimum population base standard of 100,000;
2. The establishment of diagnostic cardiac catheterization services with a caseload of 300 diagnostic catheterization procedures;
3. The establishment of therapeutic cardiac catheterization services with a caseload of 450 diagnostic and therapeutic catheterization procedures;
4. The establishment of open-heart surgery programs with a caseload of 150 open-heart surgeries; and,
5. A minimum utilization of equipment/services at existing providers of 450 cardiac catheterizations, diagnostic and therapeutic, and when applicable, 150 open-heart surgeries.

The MSDH also adopted a provision that it shall not consider utilization of equipment/services at any hospital owned and/or operated by the state or its agencies when reviewing CON applications. The MSDH further adopted standards requiring an applicant to report information regarding catheterization and open-heart program so as to monitor the provision of care to the medically underserved and the quality of that care.

The MSDH shall interpret and implement all standards in this *Plan* in recognition of the stated findings and so as to achieve the stated goal.

**Policy Statement Regarding Certificate of Need Applications
for the Acquisition or Otherwise Control of Cardiac Catheterization
Equipment and/or the Offering of Cardiac Catheterization Services**

1. Cardiac Catheterization Services: For purposes of the following CON criteria and standards, the term "cardiac catheterization services" or "catheterization services" shall include diagnostic cardiac catheterization services and therapeutic cardiac catheterization services.
 - a. "Diagnostic cardiac catheterization" services are defined as, and refer to, cardiac catheterization services which are performed for the purpose of diagnosing, identifying, or evaluating cardiac related illness or disease. Diagnostic cardiac catheterization services include, but are not limited to, left heart catheterizations, right heart catheterizations, left ventricular angiography, coronary procedures, and other cardiac catheterization services of a diagnostic nature. Diagnostic cardiac catheterization services do **not** include percutaneous transluminal coronary angioplasty (PTCA), transseptal puncture, transthoracic left ventricular puncture, myocardial biopsy, and other cardiac catheterization procedures performed specifically for therapeutic, as opposed to diagnostic, purposes.
 - b. "Therapeutic cardiac catheterization" services are defined as, and refer to, cardiac catheterization services which are performed for the purpose of actively treating, as opposed to merely diagnosing, cardiac-related illness or disease. Therapeutic cardiac catheterization services include, but are not limited to, PTCA, transseptal puncture, transthoracic left ventricular puncture and myocardial biopsy.
2. Open-Heart Surgery Capability: The MSDH shall not approve CON applications for the establishment of therapeutic cardiac catheterization services at any facility that does not have open-heart surgery capability; i.e., new therapeutic cardiac catheterization services may not be established and existing therapeutic cardiac catheterization services may not be extended without approved and operational open-heart surgery services in place. This policy does not preclude approval of a Certificate of Need application proposing the concurrent establishment of both therapeutic cardiac catheterization and open-heart surgery services.
3. Service Areas: The need for cardiac catheterization equipment/services shall be determined using the seven designated Cardiac Catheterization/Open-Heart Surgery Planning Areas (CC/OHSPAs) presented in this chapter of the *Plan*. Map XI-2 shows the CC/OHSPAs.
4. CC/OHSPA Need Determination: The need for cardiac catheterization equipment/ services within a given CC/OHSPA shall be determined independently of all other CC/OHSPAs.
5. Pediatric Cardiac Catheterization: Because the number of pediatric patients requiring study is relatively small, the provision of cardiac catheterization for neonates, infants, and young children shall be restricted to those facilities currently providing the service. National standards indicate that a minimum of 150 cardiac catheterization cases should be done per year and that catheterization of infants should not be performed in facilities which do not have active pediatric cardiac-surgical programs.
6. Present Utilization of Cardiac Catheterization Equipment/Services: The MSDH shall consider utilization of existing equipment/services and the presence of valid CONs for equipment/services within a given CC/OHSPA when reviewing CON applications. The

MSDH shall not consider utilization of equipment/services at any hospital owned and/or operated by the state or its agencies when reviewing CON applications. The Mississippi State Department of Health may collect and consider any additional information it deems essential, including information regarding access to care, to render a decision regarding any application.

7. CON Application Analysis: At its discretion, the Department of Health may use market share analysis and other methodologies in the analysis of a CON application for the acquisition or otherwise control of cardiac catheterization equipment and/or the offering of cardiac catheterization services. The Department shall not rely upon market share analysis or other statistical evaluations if they are found inadequate to address access to care concerns.
8. Minimum CC/OHSPA Population: A minimum population base of 100,000 is required for applications proposing the establishment of cardiac catheterization services. The total population within a given CC/OHSPA shall be used when determining the need for services. Population outside an applicant's CC/OHSPA will be considered in determining need only when the applicant submits adequate documentation acceptable to the Mississippi State Department of Health, such as valid patient origin studies.
9. Minimum Caseload: Applicants proposing to offer adult diagnostic cardiac catheterization services must be able to project a caseload of at least 300 diagnostic catheterizations per year. Applicants proposing to offer adult therapeutic cardiac catheterization services must be able to project a caseload of at least 450 catheterizations, diagnostic and therapeutic, per year.
10. Residence of Medical Staff: Cardiac catheterizations must be under the control of and performed by personnel living and working within the specific hospital area. No site shall be approved for the provision of services by traveling teams.
11. Hospital-Based: All cardiac catheterizations and open-heart surgery services shall be located in acute care hospitals. The MSDH shall not approve Certificate of Need applications proposing the establishment of cardiac catheterization/open-heart surgery services in freestanding facilities or in freestanding ambulatory surgery facilities.

**Certificate of Need Criteria and Standards for the Acquisition
or Otherwise Control of Diagnostic Cardiac Catheterization
Equipment and/or the Offering of
Diagnostic Cardiac Catheterization Services**

The Mississippi State Department of Health will review applications for a Certificate of Need for the acquisition or otherwise control of diagnostic cardiac catheterization equipment and/or the offering of diagnostic cardiac catheterization services under the applicable statutory requirements of Sections 41-7-173, 41-7-191, and 41-7-193, Mississippi Code of 1972, as amended. The MSDH will also review applications for Certificate of Need according to the general criteria listed in the *Mississippi Certificate of Need Review Manual*; all adopted rules, procedures and plans of the Mississippi State Department of Health; and the specific criteria and standards listed below.

The acquisition or otherwise control of diagnostic cardiac catheterization equipment is reviewable if the equipment costs in excess of \$1,500,000. The offering of diagnostic cardiac catheterization services is reviewable if the proposed provider has not provided those services on a regular basis within the period of twelve (12) months prior to the time such services would be offered.

1. **Need Criterion:** The applicant shall document a minimum population base of 100,000 in the CC/OHSPA where the proposed diagnostic cardiac catheterization equipment/service is to be located. Division of Health Planning and Resource Development population projections shall be used.
2. **Minimum Procedures:** An applicant proposing the establishment of diagnostic cardiac catheterization services only shall demonstrate that the proposed equipment/service utilization will be a minimum of 300 diagnostic cardiac catheterizations per year by its third year of operation.
3. **Impact on Existing Providers:** An applicant proposing to acquire or otherwise control diagnostic cardiac catheterization equipment and/or offer diagnostic cardiac catheterization services shall document that each existing unit, which is (a) in the CC/OHSPA and (b) within forty-five (45) miles of the applicant, has been utilized for a minimum of 450 procedures (both diagnostic and therapeutic) per year for the two most recent years as reflected in data supplied to and/or verified by the Mississippi State Department of Health. No hospital owned and/or operated by the state or its agencies shall be considered an existing unit in the CC/OHSPA under this section. The Mississippi State Department of Health may collect and consider any additional information it deems essential, including information regarding access to care, to render a decision regarding any application.
4. **Staffing Standards:** The applicant shall document that it has, or can obtain, the ability to administer the proposed services, provide sufficiently trained and experienced professional staff, and evaluate the performance of the programs. Mississippi State Department of Health staff shall use guidelines presented in *Optimal Resources for Examination of the Heart and Lungs: Cardiac Catheterization and Radiographic Facilities*, published under the auspices of the Inter-Society Commission for Heart Disease Resources, as resource materials when reviewing these items in an application.
5. **Staff Residency:** The applicant shall certify that medical staff performing diagnostic cardiac catheterization procedures shall reside within forty-five (45) minutes normal driving time of the facility.

6. Recording and Maintenance of Data: Applicants shall provide, as required under licensure standards, written assurance that they will record and maintain utilization data for diagnostic cardiac catheterization procedures (e.g., morbidity data, number of diagnostic cardiac catheterization procedures performed, and mortality data, all reported by race, sex, and payor status) and make such data available to the Mississippi State Department of Health annually.
7. Referral Agreement: An applicant proposing the establishment of diagnostic cardiac catheterization services only shall document that a formal referral agreement with a facility for the provision of emergency cardiac services (including open-heart surgery) will be in place and operational at the time of the inception of cardiac catheterization services.
8. Patient Selection: An applicant proposing to provide diagnostic cardiac catheterization services must (a) delineate the steps which will be taken to insure that high-risk or unstable patients are not catheterized in the facility, and (b) certify that therapeutic cardiac catheterization services will not be performed in the facility unless and until the applicant has received CON approval to provide therapeutic cardiac catheterization services.
9. Regulatory Approval: Before utilizing or providing the equipment or service, the applicant desiring to provide the diagnostic cardiac catheterization equipment or service shall have CON approval or written evidence that the equipment or service is exempt from CON approval as determined by the Mississippi State Department of Health. Each specified piece of equipment must be exempt from or have CON approval.

**Certificate of Need Criteria and Standards
for the Acquisition or Otherwise Control
of Therapeutic Cardiac Catheterization Equipment
and/or the Offering Of Therapeutic Cardiac Catheterization Services**

The Mississippi State Department of Health will review applications for a Certificate of Need for the acquisition or otherwise control of therapeutic cardiac catheterization equipment and/or the offering of therapeutic cardiac catheterization services under the applicable statutory requirements of Sections 41-7-173, 41-7-191, and 41-7-193, Mississippi Code of 1972, as amended. The MSDH will also review applications for Certificate of Need according to the general criteria listed in the *Mississippi Certificate of Need Review Manual*; all adopted rules, procedures and plans of the Mississippi State Department of Health; and the specific criteria and standards listed below.

The acquisition or otherwise control of therapeutic cardiac catheterization equipment is reviewable if the equipment costs in excess of \$1,500,000. The offering of therapeutic cardiac catheterization services is reviewable if the proposed provider has not provided those services on a regular basis within the period of twelve (12) months prior to the time such services would be offered.

1. **Need Criterion:** The applicant shall document a minimum population base of 100,000 in the CC/OHSPA where the proposed therapeutic cardiac catheterization equipment/service is to be located. Division of Health Planning and Resource Development population projections shall be used.
2. **Minimum Procedures:** An applicant proposing the establishment of therapeutic cardiac catheterization services shall demonstrate that the proposed equipment/service utilization will be a minimum of 450 cardiac catheterizations, both diagnostic and therapeutic, per year by its third year of operation. An applicant proposing the establishment of therapeutic cardiac catheterization services who presently offers only diagnostic cardiac catheterization may include in its demonstration of a minimum of 450 cardiac catheterizations per year the number of diagnostic catheterizations that it performs.
3. **Impact on Existing Providers:** An applicant proposing to acquire or otherwise control therapeutic cardiac catheterization equipment and/or offer therapeutic cardiac catheterization services shall document that each existing unit which is (a) in the CC/OHSPA and (b) within 45 miles of the applicant, has been utilized for a minimum of 450 procedures (both diagnostic and therapeutic) per year for the two most recent years as reflected in data supplied to and/or verified by the Mississippi State Department of Health. No hospital owned and/or operated by the state or its agencies shall be considered an existing unit in the CC/OHSPA under this section. The Mississippi State Department of Health may collect and consider any additional information it deems essential, including information regarding access to care, to render a decision regarding any application.
4. **Staffing Standards:** The applicant shall document that it has, or can obtain, the ability to administer the proposed services, provide sufficiently trained and experienced professional staff, and evaluate the performance of the programs. Mississippi State Department of Health staff shall use guidelines presented in *Optimal Resources for Examination of the Heart and Lungs: Cardiac Catheterization and Radiographic Facilities*, published under the auspices of the Inter-Society Commission for Heart Disease Resources, as resource materials when reviewing these items in an application.

5. Staff Residency: The applicant shall certify that medical staff performing therapeutic cardiac catheterization procedures shall reside within forty-five (45) minutes normal driving time of the facility.
6. Recording and Maintenance of Data: Applicants shall provide, as required under licensure standards, written assurance that they will record and maintain separate utilization data for diagnostic and therapeutic cardiac catheterization procedures (e.g., morbidity data, number of diagnostic and therapeutic cardiac catheterization procedures performed and mortality data, all reported by race, sex and payor status) and make that data available to the Mississippi State Department of Health annually.
7. Open-Heart Surgery: An applicant proposing the establishment of therapeutic cardiac catheterization services shall document that open-heart surgery services are available or will be available on-site where the proposed therapeutic cardiac catheterization services are to be offered before such procedures are performed.
8. Regulatory Approval: Before utilizing or providing the equipment or service, the applicant desiring to provide the cardiac catheterization equipment or service shall have CON approval or written evidence that the equipment or service is exempt from CON approval as determined by the Mississippi State Department of Health. Each specified piece of equipment must be exempt from or have CON approval.
9. Applicants Providing Diagnostic Catheterization Services: An applicant proposing the establishment of therapeutic cardiac catheterization services, who is already an existing provider of diagnostic catheterization services, shall demonstrate that its diagnostic cardiac catheterization unit has been utilized for a minimum of 300 procedures per year for the two most recent years as reflected in the data supplied to and/or verified by the Mississippi State Department of Health.

**Policy Statement Regarding Certificate of Need Applications
For the Acquisition of Open-Heart Surgery Equipment and/or
the Offering of Open-Heart Surgery Services**

1. Service Areas: The need for open-heart surgery equipment/services shall be determined using the seven designated Cardiac Catheterization/Open-Heart Surgery Planning Areas (CC/OHSPAs) presented in this chapter of the *Plan*. Map XI-2 shows the CC/OHSPAs.
2. CC/OHSPA Need Determination: The need for open-heart surgery equipment/services within a given CC/OHSPA shall be determined independently of all other CC/OHSPAs.
3. Pediatric Open-Heart Surgery: Because the number of pediatric patients requiring open-heart surgery is relatively small, the provision of open-heart surgery for neonates, infants, and young children shall be restricted to those facilities currently providing the service.
4. Present Utilization of Open-Heart Surgery Equipment/Services: The Mississippi State Department of Health shall consider utilization of existing open-heart surgery equipment/services and the presence of valid CONs for open-heart surgery equipment/services within a given CC/OHSPA when reviewing CON applications. The MSDH shall not consider utilization of equipment/services at any hospital owned and/or operated by the state or its agencies when reviewing CON applications. The Mississippi State Department of Health may collect and consider any additional information it deems essential, including information regarding access to care, to render a decision regarding any application.
5. CON Application Analysis: At its discretion, the Department of Health may use market share analysis and other methodologies in the analysis of a CON application for the acquisition or otherwise control of open-heart surgery equipment and/or the offering of open-heart surgery services. The Department shall not rely upon market share analysis or other statistical evaluations if they are found inadequate to address access to care concerns.
6. Minimum CC/OHSPA Population: A minimum population base of 100,000 in a CC/OHSPA (as projected by the Division of Health Planning and Resource Development) is required before such equipment/services may be considered. The total population within a given CC/OHSPA shall be used when determining the need for services. Population outside an applicant's CC/OHSPA will be considered in determining need only when the applicant submits adequate documentation acceptable to the Mississippi State Department of Health, such as valid patient origin studies.
7. Minimum Caseload: Applicants proposing to offer adult open-heart surgery services must be able to project a caseload of at least 150 open-heart surgeries per year.
8. Residence of Medical Staff: Open-heart surgery must be under the control of and performed by personnel living and working within the specific hospital area. No site shall be approved for the provision of services by traveling teams.

Certificate of Need Criteria and Standards for the Acquisition or Otherwise Control of Open-Heart Surgery Equipment and/or the Offering of Open-Heart Surgery Services

The Mississippi State Department of Health will review applications for a Certificate of Need for the acquisition or otherwise control of open-heart surgery equipment and/or the offering of open-heart surgery services under the applicable statutory requirements of Sections 41-7-173, 41-7-191, and 41-7-193, Mississippi Code of 1972, as amended. The MSDH will also review applications for Certificate of Need according to the general criteria listed in the *Mississippi Certificate of Need Review Manual*; all adopted rules, procedures and plans of the Mississippi State Department of Health; and the specific criteria and standards listed below.

The acquisition or otherwise control of open-heart surgery equipment is reviewable if the equipment cost in excess of \$1,500,000. The offering of open-heart surgery services is reviewable if the proposed provider has not provided those services on a regular basis within twelve (12) months prior to the time such services would be offered.

1. **Need Criterion:** The applicant shall document a minimum population base of 100,000 in the CC/OHSPA where the proposed open-heart surgery equipment/service is to be located. Division of Health Planning and Resource Development population projections shall be used.
2. **Minimum Procedures:** The applicant shall demonstrate that it will perform a minimum of 150 open-heart surgeries per year by its third year of operation.
3. **Impact on Existing Providers:** An applicant proposing to acquire or otherwise control open-heart surgery equipment and/or offer open-heart surgery services shall document that each facility offering open-heart surgery services which is (a) in the CC/OHSPA and (b) within 45 miles of the applicant, has performed a minimum of 150 procedures per year for the two most recent years as reflected in data supplied to and/or verified by the Mississippi State Department of Health. No hospital owned and/or operated by the state or its agencies shall be considered an existing unit in the CC/OHSPA under this section. The Mississippi State Department of Health may collect and consider any additional information it deems essential, including information regarding access to care, to render a decision regarding any application.
4. **Staffing Standards:** The applicant shall document that it has, or can obtain, the ability to administer the proposed services, provide sufficiently trained and experienced professional staff, and evaluate the performance of the programs. Department of Health staff shall use guidelines presented in *Optimal Resources for Examination of the Heart and Lungs: Cardiac Catheterization and Radiographic Facilities*, published under the auspices of the Inter-Society Commission for Heart Disease Resources, and *Guidelines and Indications for Coronary Artery Bypass Graft Surgery: A Report of the American College of Cardiology/American Heart Association Task Force on Assessment of Diagnostic and Therapeutic Cardiovascular Procedures (Subcommittee on Coronary Artery Bypass Graft Surgery)*, published under the auspices of the American College of Cardiology, as resource materials when reviewing these items in an application.
5. **Staff Residency:** The applicant shall certify that medical staff performing open-heart surgery procedures shall reside within forty-five (45) minutes normal driving time of the

facility. The applicant shall document that proposed open-heart surgery procedures shall not be performed by traveling teams.

6. Recording and Maintenance of Data: Applicants shall provide, as required under licensure standards, written assurance that they will record and maintain utilization data for open-heart surgeries (e.g., morbidity data, number of open-heart surgeries performed and mortality data, all reported by race, sex and payor status) and make such data available to the Mississippi State Department of Health annually.
7. Regulatory Approval: Before utilizing or providing the equipment or service, the applicant desiring to provide the open-heart surgery equipment or service shall have CON approval or written evidence that the equipment or service is exempt from CON approval as determined by the Mississippi State Department of Health. Each specified piece of equipment must be exempt from or have CON approval.

Map XI-2
**Cardiac Catheterization/Open-Heart Surgery
 Planning Areas (CC/OHSPA)**
and Location of Existing/CON-Approved Services

